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President's Commentary

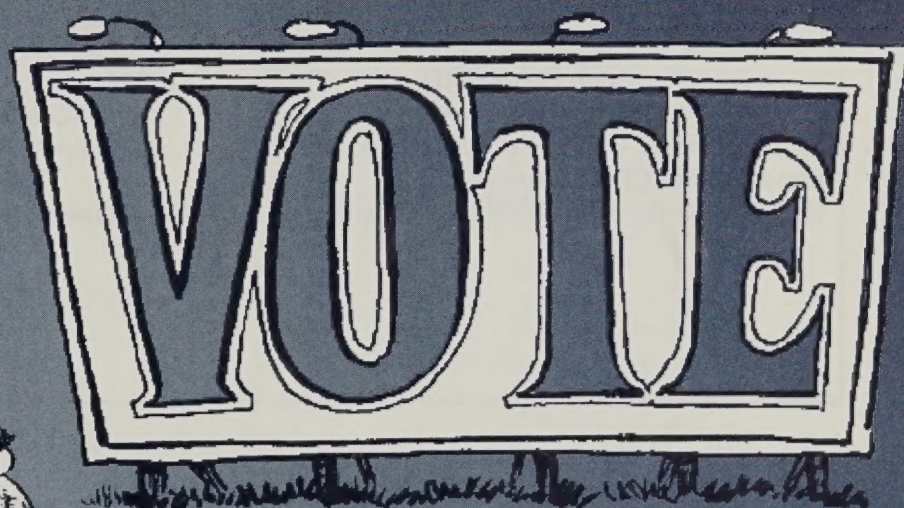
"MPhA 120th Anniversary 1882 - 2002"

2002 Maryland Leadership Elections

"Candidate Statements and
Official Ballot"

Recognizing Pharmacy Excellence

"The 2002 MPhA Awards"



2002
MPhA Elections

Maryland Pharmacists Association

650 W. Lombard Street

Baltimore, MD 21201

(410) 727-0746

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The Official Publication of the Maryland Pharmacists Association

President's Commentary 5

"MPhA 120th Anniversary 1882-2002"

Director's Column 6

"Unintended Consequences"

Point of Care Devices that Fit the Palm of Your Hand 9

Maryland's Kidney Disease Program 12

A Pharmacist's Tongue-In-Cheek Guide to Patient Etiquette 13

Statements of the Candidates 17

2002 Maryland Leadership Elections . . . 21
"Official Ballot"

Recognizing Pharmacy Excellence 24
"The 2002 MPhA Awards"

Medicaid Prescriptions 31
"Pharmacists Most Frequently asked Questions"

Continuing Education 33
Patient Counseling: "Management of Sore Throat"

Advertiser's Index

Mayer & Steinberg	30
McKessonHBOC	40
Medicine Shoppe	29
PEAC	20
Pharmacists Mutual	4
PharmaSTAT	20
RPh on the go	14
Safeway	29

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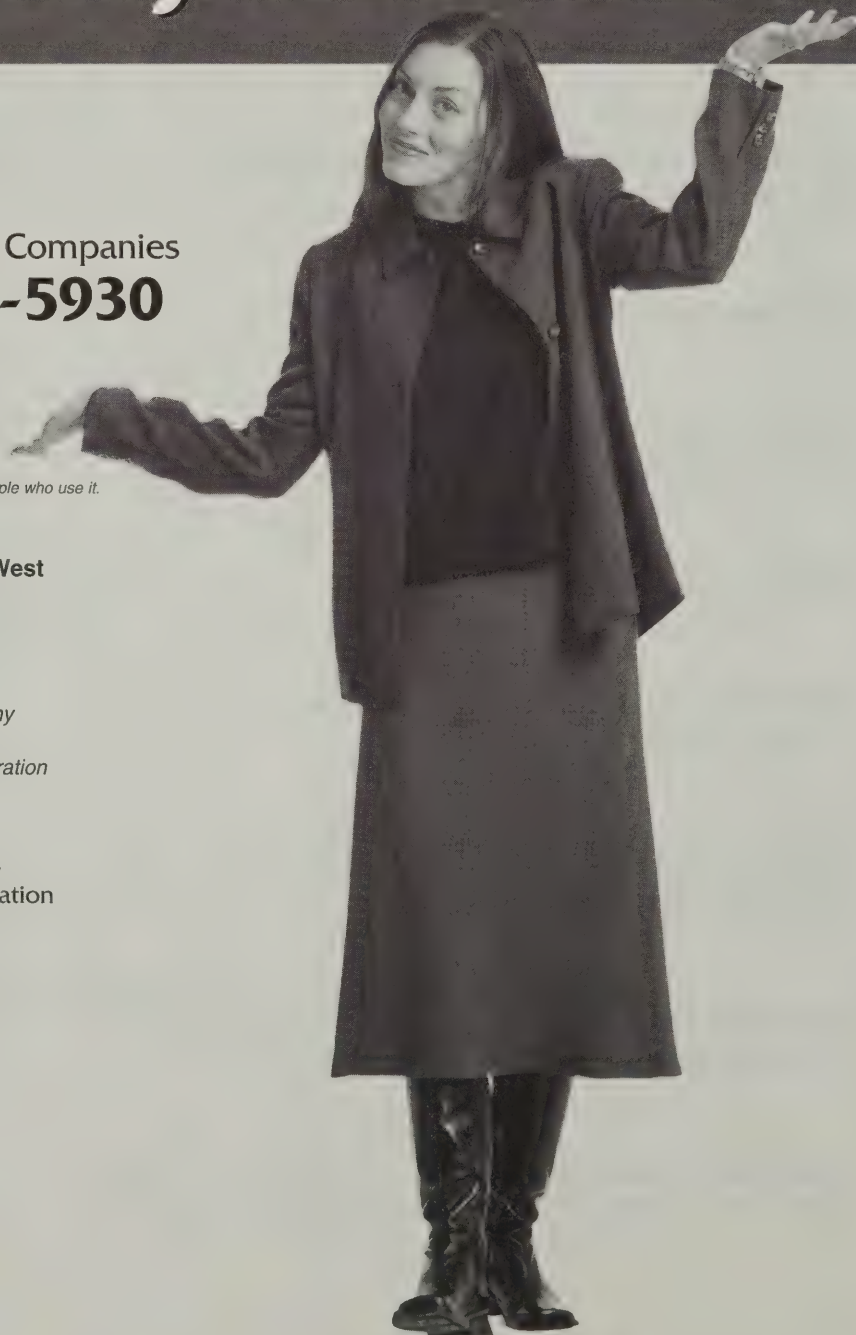
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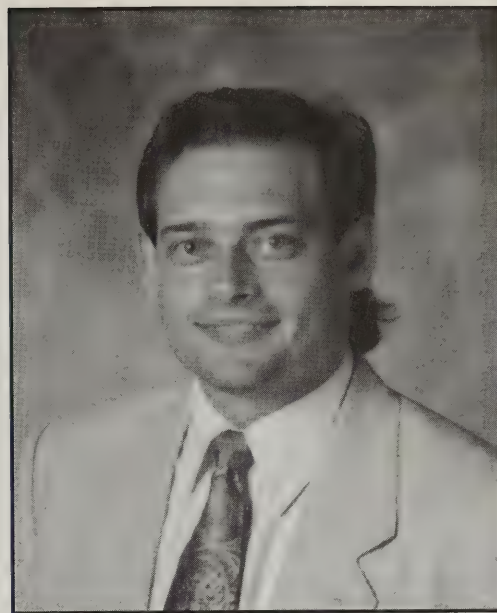
Presidents Commentary

As I write this article, it is early January of 2002. With the New Year comes the 120th anniversary of the Maryland Pharmacists Association. An anniversary is a time to celebrate the past and prepare for the future, and that is exactly what we plan to do.

It is often said that with age comes knowledge and knowledge is gained from experience. The beauty of the concept of learning from experience is that one never graduates, but rather the process perpetuates through the application of past experiences to facilitate change and growth into the future. This is certainly true of the MPhA, as we have undergone numerous changes over the years. However, we remain steadfast in our commitment to serve our members, represent all pharmacists (regardless of practice setting), and promote the highest standards of professional practice.

While the MPhA is 120 years old, we are still a very young and vibrant organization undergoing continual change and evolution. This is a direct result of the rapidly changing environment of the profession of pharmacy and healthcare in general, both of which are centuries old, and in comparison, foreshadow the MPhA as if it were a mere sapling in the healthcare forest.

It is essential that we cultivate our 120-year young organization. Each of us has an important role to play in fostering the growth of our Association and the accompanying strength as we grow not only in age, but also in numbers. We must be persistent in our pursuit and insistent on the participation and involvement of our fellow pharmacists.



Mark Sanford, P.D., President

We are the present, and it is our awesome responsibility to learn from the past, apply the wisdom of our predecessors, and plant the seeds of the future. Through this process we will ensure the longevity of MPhA for the next 120 years and beyond, ensuring that the profession will reap the benefits.

As we continue our pursuit of shaping the future of pharmacy, it is equally important that we preserve the past and remember the heritage of our profession. As we prepare for the future of the MPhA, we are committed to preserving the past. Amidst all of the forward thinking, proactive initiatives that the MPhA undertakes on behalf of pharmacy and pharmacists, an enormous fundraising effort is about to be kicked-off to support the continued pursuit of the future and celebrate the past through preservation and display of an 1800's pharmacy and a 1950's pharmacy with a fully functional soda fountain as a focal point of the Kelly Memorial Building in Baltimore Maryland, our Association's headquarters.

The future is what we make it. Please help the cause. Be an active member of the Association. Recruit a new member. Contribute to the preservation of the past and the pursuit of the future. All of the efforts that we undertake today will preserve our heritage, cultivate our future, and prove to make MPhA one of the mighty oaks in the healthcare forest of tomorrow.



Howard Schiff
Executive Director

Directors' Column

Unintended Consequences

Because of a higher number of recipients, higher utilization and a higher cost of prescription drugs, the General Assembly is looking at budget shortfalls in the Medicaid pharmacy program. Although 75-80% of Medicaid recipients are relegated to the HealthChoice program (the managed care portion), far more funds are expended for the Medicaid program. Additionally, because of the recession, the entire state budget is underfunded.

Although most legislators seem to understand and sympathize with pharmacy owners, they apparently fail to realize the unintended consequences of reimbursement cost cutting.

When a for-profit pharmacy, as in any other business, sees profits dwindle, expenses are cut. For some, this means cuts in pharmacy staff with the concomitant increase in workload, consumer

complaints, pharmacist "burn-out" and the possibility of patient safety compromises. For others it means cuts in services such as delivery or hours.

Last year 30 pharmacies in Baltimore City and Baltimore County closed. Many of these were in areas heavy with Medicaid recipients. Although apparently few recipients know it, the program pays for transportation for medical services. As cuts come and a pharmacy owner realizes it will be unable to be profitable, the pharmacy closes and the Medicaid recipient must either travel at state expense or do without medications. Consequently, the state will spend more for transportation and/or emergency rooms and hospitals than it saves from pharmacy cuts. Further though the cutbacks on long-term care have not been delineated, they could be devastating.

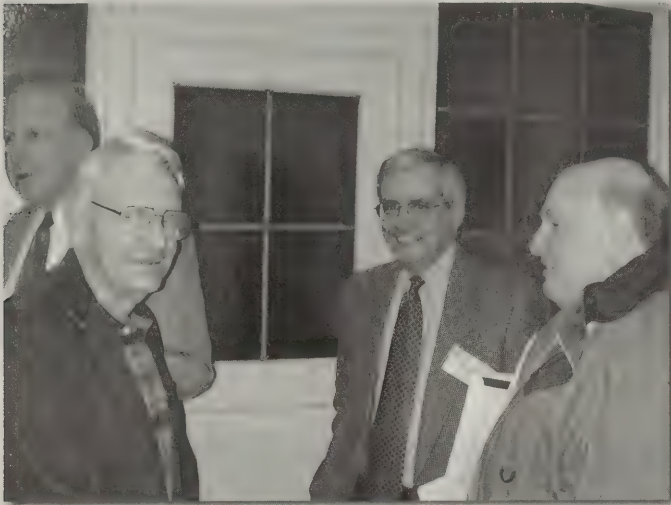
The legislature and the Bush administration are also considering some sort of discount card program for seniors and the uninsured. Admirable in their intent as they may be, these cards put the onus on pharmacy to absorb the costs. But, as one legislative aide asked, what alternative program can you suggest that won't cost the government money? Certainly these cards will add to the administrative burden of the pharmacist as he/she sorts out the various manufacturer and government sponsored discount cards and attempts to adjudicate a prescription claim.

Politicians don't look too far ahead in an election and redistricting year. Our concerns are heard but get lost in the need for action in order to show voters how much is being done. Further, pharmacy permit holders are very competitive and would rather go out of business than refuse to accept a program with a certain demographic mass. As this is written, there are approximately 30 days till the end of the legislative session. We can only hope that the state and federal governments see that we're the "good guys" and have much to offer to improve health care, reduce administrative burdens and reduce program costs.

Maryland Pharmacists Association

120th Anniversary Reception

February 10, 2002





Point of Care Devices that Fit the Palm of Your Hand

Bill G. Felkey

Assistant Professor of Pharmacy Care Systems

Auburn University, AL

In 1982, when IBM introduced the PC, many were asking, "What in the world would I ever do with one of those?" Many discovered that there was much to do on a personal computer and now most of us find it hard to imagine working without a computer workstation on a desk or a notebook computer on their shoulder when they travel. In the 1990's we added the internet to the equation. In 1999, more information existed on the Internet than in the entire history of print for mankind. When my home cable modem went down last week, I felt disconnected from the world. When I awoke at 3 a.m., I had nothing to do but try to go back to sleep. Dial-up access you ask? Please don't make me go back there.

The basic purpose of information is to reduce uncertainty. Combining needed information with extreme portability gives us the power we all hope to derive from the technologies we embrace. A similar kind of technology revolution to the PC explosion is now taking place in palmtops. We started out slowly with portable organizer technology. Early adopters embraced their Sharp Wizards, Hewlett-Packard 100's, and Casio BOSS's as many as 10 years ago. My colleagues made fun of me when I took out my Casio and converted little slips of paper containing names and telephone numbers into database entries. I got a lot of satisfaction when my address book database grew to over 1400 entries and guess who my colleagues seek when they need a phone number or a contact.

Palm technologies are currently taking the pharmacy and medical professions by storm. Literally tens of thousands of pharmacists and physicians are now "packing" a Palm OS or Windows CE device in their shirt pocket, lab coat or purse. Over 80 percent of these palmtop devices are Palm OS. In medicine and pharmacy, the majority of applications are available in the Palm OS. I am reminded of the battle fought by VHS and Beta formats in video cassette recorders (Beta was technologically superior but VHS won out due in part to a six-hour tape capacity). I advise a careful consideration of functional requirements for the palmtop device as well as careful identification of software required in a practice before making a purchase decision. This is a dynamic market and buyers can expect to migrate to superior platforms every few years as efficiency and effectiveness gains achieved in the new units are accompanied by improved features and benefits that compel us forward.

Palmtop devices also allow us health care types to consider that a new "infrastructure" exists to solve problems. The pharmacists using these devices no longer have to say, when confronted with a drug-related question, "I'll get back to you on that." Their medical counterparts are calling hospital pharmacists "geniuses" after rounds. The pharmacists who are asked by patients at social functions, "Oh, you're a pharmacist?" can now reach into a pocket or purse and reply, "YES, I AM!" Physicians have finally found a reason to carry

a piece of technology that benefits them personally and professionally. When I do seminars for physicians and expose them to more than 490 palmtop applications that are available for medicine, they won't let me continue with my presentation until they fully explore how to acquire these devices and applications.

One thing is certain, as we move forward into wireless connected, portable technologies that weigh less and do more, we have an exciting future to anticipate. Create a strategic and tactical mapping of how information flows in your organization and consider a real-time connectivity between all associated parties in a health care enterprise. In this information age, what will mean to a pharmacist to receive a legible, "cleaned up" prescription where formulary, therapeutic, and eligibility issues are addressed prior to the prescription's arrival in the pharmacy? What will it mean to have a peer reviewed, updated drug and medical compendia available at the point of care? What will it mean to have read and write access to a palmtop electronic medical record? How will patient education roles be enhanced? How will the Internet impose a global perspective on all of our activities? Is the price on the item you are holding in the checkout line for the cashier to ring up the very best on the planet today?

Have I convinced you to look further? Excuse me, my palmtop just alerted me to a conference call I'm supposed to take.

Selecting your Personal Digital Assistant (PDA): The Way We See It

By Bill G. Felkey, Associate Professor and Brent I. Fox, Infomatics Research Associate
School Pharmacy, Pharmacy Care Systems, Auburn University

One of the most frequently asked questions we get from pharmacists is, "What is the best PDA for me to buy?" We always know the answer to the question for us individually, but it takes a little bit of time to find an appropriate answer for anyone else. Answer this, "If you were going to take a trip, would you go through Duluth, MN?" The definite response is, "It depends on where you are going," on PDA purchases, if you do not know where you are going, then any PDA might do. Here are the factors that we think are the most important questions you'll need to answer to let us help you select the best PDA for you.

Do you know what software you will need to run on your PDA?

Entry level users may only wish to purchase a low cost PDA as a digital day planner. We think pharmacists need something more than the lowest model. For example, having core medical and drug information with you at all times for evidence-based healthcare would demand a larger (8MB) memory unit. The good news is that if you decide to get any unit, the price of all PDA's is expected to drop, some to less than \$100. The most basic PDA provides users with an address book, calendar program, to do list, calculator, memo pad, expense recorder, and E-mail reader. Disciplined users should be able to totally eliminate little pieces of paper from their lives. All PDA formats have similar functions as organizers.

Selection of the PDA family or operating system should be done on the basis of the availability of software in the individual format. At present, in medicine and pharmacy, the PDA operating system with the best software coverage is the Palm OS. It has over 490 medical applications, thousands of business applications, and tens of thousands of documents and e-books available. In second place, Windows CE (Pocket PC) covers about 30 percent of the health applications available. Pocket PC's are more multimedia capable and are usually larger in size. PC Magazine predicts Pocket PC's to grow to about 40% market penetration in the next three years as compared to Palm OS dropping to 45%. Windows CE units try to operate more like a PC than a complementary organizer, but they can suffer from windows lock-up/crash problems too.

The battle for supremacy between Palm and Windows CE units will continue for the next few years. At this point in time it is our position that the coverage of software and the fact that 82% of all PDA users in healthcare use Palm OS makes this format the current winner. However, if units like the Compaq Ipaq 3670 are calling your name, you need to identify all of the potential functions and software that you can see yourself needing and make sure that all of these assets are available in the format that you select. Moreover, if the organization you work for actually supports one format over the other,

this should become a very important selection criterion.

Is having a backlit color screen important to you?

There are monotone and color screens available on palmtops. Older palms like the Palm Professional offered a lower contract (more difficult to see) screen. The monotone screen on the Palm V, Palm 500, Handspring, and Sony products all represent an improved display for Palm OS users. The best visibility, in our opinion, can be achieved on backlit color screens, but these units are somewhat more costly. The color screen is all fairly similar but the new Palm 505 is made from a special type of LCD material that can be viewed in bright sunlight.

Are expendability and multitasking modules important to you?

Only the newest of the Palm products have added expansion models. Thus, the Handspring family of PDA's is leading the expansion module department. Handspring can be a PDA plus any one other function a Visor springboard module supports. Options include modems, memory, books, cameras, GPS units, slide modules, MP-3 players, voice recorders, and cellular telephones.

How important is finding the lowest cost to you?

We both recommend the online technology, price, and features comparison database offered by Cnet, located at <http://shopper.cnet.com>. The selection of the PDA

hyperlink from the handheld category on the web page will allow shoppers to find the best price available on the planet for any listed model. Expect to see a business rating, shipping cost, stock level, toll free number, hyperlink to the

site, and date last updated. Independent comparisons are also only a click away. Top products are updated daily by sellers wishing to top the best price category.

PDA Model	OS	Display	Memory Base & Exp	Expansion Modules, #	Wireless Standard	Size	Street Price	Comment
Palm 105	Palm	Mono	8 M	No	No	SM	\$ 165	Good starter unit
Palm IIIxe	Palm	Mono	8 M	No	No	Med	\$ 161	Old design, inexpensive
Palm IIIC	Palm	Color	8 M	No	No	Med	\$ 253	Old, good color screen
Palm Vx	Palm	Mono	8 M	Yes	No	Lrg	\$ 264	Thin but not expandable
Palm VII	Palm	Mono	8 M	No	Yes	Med	\$ 267	Slow wireless
Palm 500	Palm	Mono	8 M + 16 M	Yes	No	Med	\$ 348	New and Palm
Palm 505	Palm	Color*	8 M + 16 M	Yes	No	Med	\$ 419	Color and new
Handspring Visor Deluxe	Palm	Mono	8 M + 16 M	Yes	No	Med	\$ 225	Inexpensive and great Expandable
Handspring Prism	Palm	Color	8 M + 16 M	Yes	No	Lrg	\$ 402	Thick but good screen
Handspring Platinum	Palm	Mono	8 M + 16 M	Yes	No	Med	\$ 278	Only fast processor
Handspring Edge	Palm	Mono	8 M + 16 M	Yes	No	Sm	\$ 373	Thin and use modules
TRG Pro	Palm	Mono	8 M + 1 Gig	Yes	No	Med	\$ 240	Largest memory but old style, IEEE
Sony Clie PEG 300	Palm	Mono	8 M & 64 M	Yes	No	Sm	\$ 255	Thin, jog wheel
Sony Clie PEG 500	Palm	Color	8 M + 64 M	Yes	No	Sm	\$ 500	Color and 300 features
Kyocera QCP 6035	Palm	Mono	8 M	No	Yes	Lrg	\$ 500	Combined factory cell and PDA
Compaq Ipaq 3670	Pocket PC	Color	16 M + 64 M	Yes	No	Lrg	\$ 644	Popular, Multimedia
Hewlett Packard	Windows CE	Color	64 M	Yes	No	Med	\$ 341	Various models
Psion	Proprietary	Mono	16 M + 20 M	Yes	No	Med	\$ 459	Scarce software

* Special LCD material supports use in full sunlight

Websites of interest for Palm applications:

WeSync software for calendar and contact sharing: <http://www.wesync.com>. HandBase database application:

<http://www.ddhsoftware.com/software.html?view=handbase>. HandBase prewritten medical database templates and applications:

<http://www.ddhsoftware.com/gallery.html?show=Medical>. Software for interface between HandBase and Microsoft Access: <http://www.consult-us.cc/html/handjet.us.htm>. Five minute clinical consult, Lesidrug, Interact: <http://www.lexi.com>. Free frequently updated drug database:

EpocratesRx: <http://www.epocrates.com>. E & M Coding assistant: <http://www.statcoder.com>. Websites devoted to docs who use

PDA's: <http://www.pdamd.com> <http://www.healthpalmipilot.com> <http://www.collectivemed.com/pdasource.html>: <http://www.handhelmed.com>.

Maryland's Kidney Disease Program

Did you know that as of December 20, 2001 Medicare pays for transplant drugs for those over 65 and those on Social Security Disability for the life of the graft? Medicare covers those whose transplant was due solely due to end stage renal disease, with no other qualifying disabling condition, for 36 months. That the Maryland Kidney Disease Program, as of July 13, 2001 pays for transplant drugs for all kidney transplant patients, not covered by Medicare, for the life of the graft? If you have dialysis or kidney transplant patients who are not covered by the Kidney Disease Program make sure you advise them of this Program. For an application call 410-767-5000.

Maryland's Kidney Disease Program Leads the Nation in Providing Care to ESRD Patients

For over 30 years Maryland has led the country in its treatment of end stage renal and kidney transplant citizens. In 1972 the Maryland Kidney Disease Program (KDP) was created to assure all Maryland End Stage Renal Disease (ESRD) patients of access to all medically necessary care. While KDP is the payer of last resort, with over an \$8m budget, it pays all Medicare co-payments and deductibles and all medically necessary prescription and OTC medications related to ESRD/kidney transplantation or co-morbidities associated with ESRD. For those not eligible for Medicare, KDP covers all costs.

Not only did Maryland create a Program to assure patients of all medically necessary care but created the State Commission on Kidney Disease (CKD) to assure proper oversight of each dialysis and transplant facility. While the Center for Medicare and Medicaid Services provides for the inspection of every dialysis center prior to its opening and then every few

years thereafter, Maryland provides for annual review of each facility mandating their compliance with regulations more stringent than those that CMS uses. The Commission, comprised of volunteer experts in the field of renal medicine, regularly reviews the annual reports, if necessary orders corrective action, and is available to respond to patient grievances.

Additionally the Maryland Chapter of the National Kidney Foundation educates patients on living successfully with ESRD and kidney transplantation. The Maryland Patient Advocacy Group (MPAG) actively advocates for the needs of patients who have fallen through the cracks and is currently developing a Renal GAP Program to make sure no patient ever goes without medication. Both these organizations are actively working to assure the fragile dialysis patient of door through door transportation to dialysis and back.

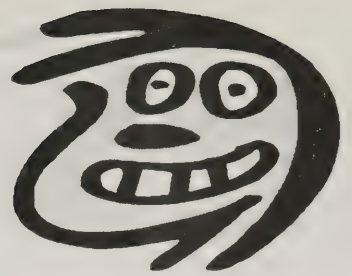
Currently Maryland has over 5700 patients being dialyzed in 115 units across the State. This number is increasing by 10% per year mainly due to un-

treated hypertension and diabetes. If Maryland is to prevent even greater numbers of patients from joining the roles of dialysis patients we must make sure to identify all those with these conditions and encourage their treatment.

Make sure and refer all dialysis and kidney transplant patients to the Maryland Kidney Disease Program 410-767-5000 for access to care and to the National Kidney Foundation 410-494-8545 for education. If your pharmacy identifies a patient in need of an advocate to access care, please refer them to MPAG at 410-653-5616.

Maryland Patient Advocacy Group
7432 Park Heights Avenue
Baltimore, Maryland 21208
410-653-5616
FAX 410-653-5615
yettapearl@home.com

A Pharmacist's Tongue-In-Cheek Guide to Patient Etiquette



1. Be sure to stare at the pharmacist while your prescriptions are being filled. Staring at the pharmacist makes him or her work faster.
2. Never remember the name of the medications you want refilled. By calling it "the little white pill," you are sure to receive the correct medication.
3. When calling in eight prescriptions or more, always arrive at the pharmacy to pick them up within 10 minutes. It is ok to hurry the pharmacists; if they make a mistake, it won't kill you or anything.
4. Feel free to ask the pharmacy staff for the exact price of your prescription before it is filled. The staff should know every co-pay for every insurance plan.
5. Always ask how long it will take to fill a prescription. If you're lucky you will get it for free if it's not ready in 30 minutes or less. Also, be sure to keep asking if the prescription is ready every five minutes—pharmacists often keep prescriptions to themselves after they are filled just to tick you off.
6. Be sure to complain about the co-pay. The co-pay is set on the whim of the pharmacist and has nothing to do with the insurance company.
7. It is not necessary to present your insurance card—or even know the name of the company. Pharmacists are psychic and know everyone's insurance.
8. Pharmacies encourage forgery. When you pick up a prescription for someone else, please forge his name.
9. Upon calling in a refill for a maintenance medication without refills, always question why the doctor has to be called when you've taken the same medication for years. It is only a myth that prescription medications have to be ordered by doctors.
10. Always question why the insurance company is so concerned about your getting Prilosec 10 days too soon. After all you're paying \$5.00 for it, and that's all it costs.
11. Over-the-counter displays are put there in order to entertain children. Please encourage them to play with any item and open one or two.
12. Make sure you save all your old insurance cards. One of the pharmacist's favorite games is to guess which one is current.
13. When you call in a prescription, just say, "Can I have my pills filled?" You can be sure the pharmacist will recognize your voice and know which medication you want.
14. Pharmacists are some of the few people whose ears work independently. So when you see a pharmacist on the phone, feel free to just start talking—his free ear will hear everything.
15. The pharmacist is the only person in the store who is really capable of writing down your refill numbers, so when you call demand to speak to the pharmacist.
16. Try to do all your pharmacy business on a Monday. The pharmacist will appreciate it.
17. Another pharmacist favorite is to have a patient walk up and ask "Can I pick up a prescription?" Guessing who you are is another pharmacist game.
18. When there are several people ahead of you near the pick up counter, always stand right at it. The pharmacist will know how important you are and fill your Rx first, and if not, you can listen to juicy patient-pharmacist conversations.
19. If you are not asked for your insurance card, it means that the pharmacist wants to fill your prescription and then, after you are told how much it is you can shout, "I have insurance." The pharmacist will be glad to do it over.

20. When you need a really old prescription filled, tell the pharmacists that you have a standing order for it. This works especially well if the doctor who wrote it is dead.

21. When you get a new insurance card, make sure you keep it a secret. The pharmacist would rather phone your old company to find out why your Rx is being rejected.

22. When you drop off a refill bottle, tell the pharmacist you'll pick it up either today or tomorrow. This type of clarity helps him plan his workload.

23. When you order your prescriptions and the pharmacist asks which ones, respond by saying, "All of them." He will know.

24. When you're asked for the number of your prescription, respond by saying, "I don't know, you have it there." The pharmacist will know.

25. When asking for a refill on pain medication, make sure you wait until the last one is gone and then try to call late on Friday afternoon. It will be easy for the pharmacist to get in touch with the doctor for a new Rx.

—By Jon Marcaccini, R.Ph.
Community Pharmacist in
Minnesota

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Lack of Medication Dose Uniformity in Commonly Split Tablets¹

Paper Summary by Clara K. Song Pharm.D Candidate 2002

Health care professionals sometimes instruct patients to split tablets into halves or quarters in an effort to titrate doses or reduce costs. Some managed care organizations have promoted the splitting of double-strength tablets to reduce medication costs.²

Recommendations to split whole tablets into halves rest on the assumption that the tablet will be split with sufficient accuracy. However, Stimpel et al³ showed that a majority of antihypertensive tablets did not break evenly, despite being scored. Sedrati et al⁴ identified several tablet products that, when split, resulted in half-tablets with doses outside an 85% to 115% range of the target half dose. McDevitt et al⁵ evaluated the ability of healthy volunteers to split HCTZ tablets. More than 40% of the resulting split tablets deviated by 10% or more from the target weight, and more than 10% of the split tablets deviated by at least 20%.

An important public health standard for prescription medications is the Uniformity of Dosage Units test in the United States Pharmacopeia 24 (USP).⁶ This test requires relatively uniform drug content from tablet to tablet, essentially ensuring that the vast majority of individual tablets contain between 85% and 115% of the labeled dose while allowing for 6% relative standard deviation (RSD) in drug content.

The objective of this study was to split 11 commonly split tablets and evaluate whether the resulting half-tablets provided equal doses, based on a liberal adaptation of the USP Uniformity of Dosage Units test. These 11 tablets were chosen through anecdotal reports of which products are commonly split in practice.

Results showed that of the 11 tablet products evaluated, only 3 passed the uniformity test. Splitting these products produced no half-tablets with weights outside the target range of 85% to 115%. Each product also showed RSD less than 10%. The key thing to notice here is that these products shared no common visible physical tablet characteristic that could explain their uniformity when split. The eight products that failed the test failed for different reasons, whether having too many half-tablets outside the target range or having RSD greater than 10%. Like the three products that passed out uniformity test, these eight products shared no common visible physical characteristic that could explain their failure.

Our results strongly suggest that split tablets generally fail to meet expectations for content uniformity. While we would agree that the therapeutic ranges of most tablet products are large enough to guard against complications from even twofold variations in dosing, we recommend against the general practice of splitting tablets.

References

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5. McDevitt JT, Gurst AH, Chen Y. Accuracy of tablet splitting. *Pharmacotherapy.* 1998;18:548-7.
6. Uniformity of dosage units. *United States Pharmacopeia 24/National Formulary 19.* Rockville, Md: United States Pharmacopeial Convention, Inc.;1999:2000-3.

Pill Tiles

This is one of several fund raising efforts by the Maryland Pharmacists Association Foundation to refurbish the Kelly Memorial Building.



- Only a few pharmacists still use pill tiles in their daily practice.
- Many who compound ointments use sheets of paper rather than the traditional square tile.

Now you can purchase your own personalized pill tile. These tiles can be personalized with your name or message. It is a fitting way to commemorate yourself, a loved one, or an event. The pill tiles will be displayed in the refurbished Kelly Memorial Building.

Thank you for your support!

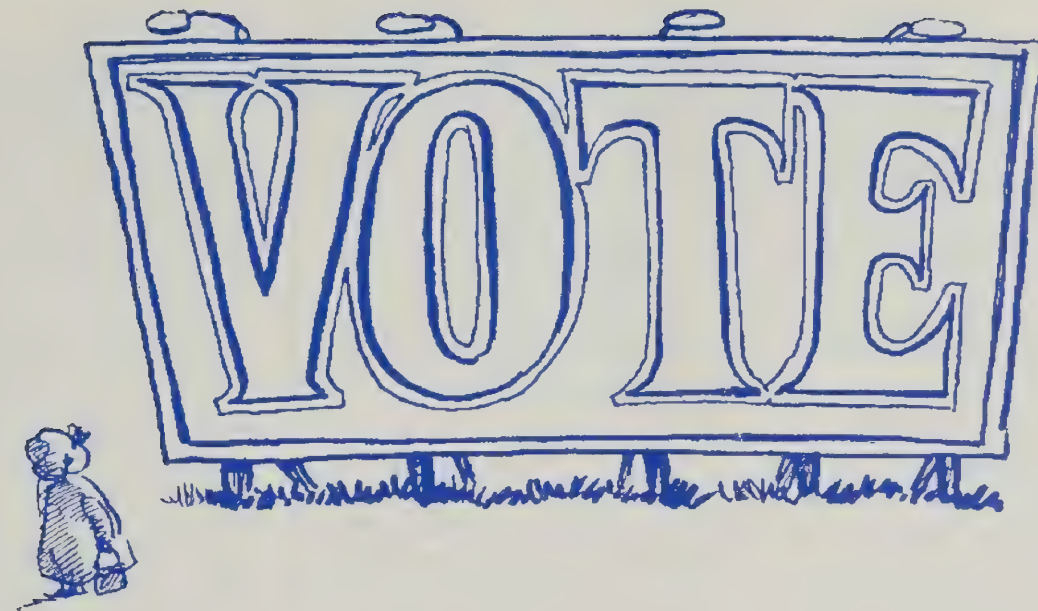
Maryland Pharmacists Association Foundation

650 W. Lombard Street
Baltimore, Maryland 21201

Phone: 410-727-0746

Fax: 410-727-2253

Email: mpha@erols.com



STATEMENTS OF THE CANDIDATES

**Position: Second Vice President
Cynthia J. Boyle, Pharm.D.**

Phone: 410-939-1809 (H)

Email: cboyle@rx.umaryland.edu

Active MPhA Involvement
Since 1978

Maryland Practice Experience:
Community Pharmacy, Health-
System Pharmacy, Pharmacy
Education

Just as a rope is stronger than its strands, MPhA is strengthened by the combined abilities, talents, and experiences of its members. In that respect, I believe the key challenge for our association is building relationships, both internal and external, as we strategize to solve pharmacy problems and public health issues.

Even statements of encouragement to fellow members are empowering in building relationships. This is best explained by an encounter with Milton Moskowitz after I had conducted the last House of Delegates meeting. Not only did he make sure to say I had done a good job, but he also said, "You have a gift." He is a man

who always means what he says, and he was surprised that his comment meant so much to me.

Among MPhA members and associates who are pharmacists, students, faculty, and citizens, we have many incredible gifts. We are fundraisers, lobbyists, advisors, savvy businesspeople, daredevils, teachers, communicators, cautious thinkers, writers, mentors, caregivers, historians, organizers, donors, and counselors. What are your unique gifts?

I believe my gifts include devotion to the profession, collaborative leadership, effective networking for MPhA and pharmacy, exposure to diverse ideas, knowledge of pharmacy in many practice settings through experiential learning, creative problem-solving, and a positive work ethic fueled by optimism. I would be honored to work with you over the next four years, and I ask for your support. I have listed my contact information if you would like to discuss your ideas and desires for MPhA as we shape the future of pharmacy in Maryland. I won't let you down.

**Position: Second Vice President
Joseph L. Marrocco, P.D.**

3909 Eland Road

Phoenix, MD 21131

Duquesne University
School of Pharmacy
Pittsburgh, PA

Graduation Year: 1973

Practice: Management-Community
Pharmacy

Employer: Giant Pharmacy

In this new millennium, as society is looking more at pharmacy to being a vital component and key player in our health care system, pharmacists are limited at the present time, in our ability to maximize our roles.

The growth and increase in sheer volume of prescriptions indicate that pharmacists today are working harder, seeing more patients, filling more prescriptions than ever, while at the same time, pharmacists knowledge, care for patient well being, and their accessibility is hardly being tapped.

With the current shortage of pharmacists, society is going to have a very difficult time receiving the full

benefit from pharmacists in the current system.

Studies by NACDS (National Association of Chain Drug Stores) indicate that nearly 70% of a pharmacist's time is spent on activities that could be done by properly trained technicians, i.e. telephone answering, counting, packaging, and labeling prescriptions, and resolving of third party insurance issues.

As Vice President of MPhA I pledge to you, my fellow colleagues in all facets of our esteemed profession, of my desire, as with yours, to insure pharmacy benefits and new drug payment systems that appropriately align financial incentives and rewards with society's needs to pharmacists to enable patients to achieve optimum outcomes of proper medication utilization with suitable drug and compliance information and monitoring.

For nearly ten years, I have enjoyed the honor and privilege to serve our profession and MPhA, as a Trustee and officer. I am committed to promulgating the goals and expectations of MPhA and our profession, and ask for your support and thank you for your consideration.

**Position: Treasurer
Joseph DeMino, P.D.**

I look forward to the honor and privilege of serving the profession of pharmacy and the state of Maryland as Treasurer of the Maryland Pharmacists Association.

My experience, my commitment of time and energy will enable me to contribute to the strength of our profession and our association.

I ask for and appreciate your support.

**Position: Trustee Seat #1
Alfred Abramson, P.D.**

9 Rush Vine Court
Owings Mills, MD 21117

University of Maryland
School of Pharmacy
Graduation Year: 1956
Practice: Teacher
Employer: University of Maryland
School of Pharmacy

I owned my own community pharmacy from 1959 to 1982. Since that time I have been teaching at the University of Maryland School of Pharmacy. I enjoy teaching young people and giving them a perspective on the "real world." The students today are intelligent and enthusiastic and I try to teach them what to expect when they go into the job market.

I have been an active member of the Board of Trustees since 1999 and have functioned as Chair of the Legislative Committee and, at times, as a representative of the school. The MPhA is a dynamic, growing organization and I like to be part of it. I believe that with my experience and outlook I bring something to the organization as a trustee. I thank you for your support.

**Position: Trustee Seat #1
Douglas Campbell**

I would be proud and honored to serve on the Board of Trustees of the Maryland Pharmacists Association. Having been a practicing pharmacist for almost 30 years in the Baltimore area, I have observed both as a Hospital, and as a Retail Pharmacist many areas in our profession where I feel a strong state pharmaceutical organization, such as MPhA can work for improvement and benefit to all of us in this fine profession of pharmacy. I would like to offer my services and enthusiasm towards working with the Board of Trustees

in working on such topics as profession reimbursements, professional relations, improved medication safety, and public health education initiatives. I am employed now as a pharmacist with PharmaSTAT, Inc., so I get to experience many, many different and interesting practice settings in pharmacy both in Maryland and Pennsylvania, so have observed and listed too many topics of current interest and concern to my fellow professionals, and would like to offer my services in a more direct way to improve and change some of these topics, by my serving on the MPhA Board of Trustees.

**Position: Trustee Seat #2
Ginger Apyar, P.D.**

130 Long Dr.
Queenstown, MD 21658

Duquesne University
School of Pharmacy, 1972
Community Practice
Happy Harry's, Inc.

These last few years I have returned to practicing our profession as a community pharmacist. This is where I started when I first graduated. I moved over from "retail" to become a managed-care pharmacist working for a large PBM. I have found from my career moves that whatever descriptive term is placed in front of the word pharmacist, we all share the same pride in our profession and also the same challenges. Being comfortable now with the term pharmaceutical care and the dynamic changes it has brought, there is still much transitioning happening to our practice of pharmacy by those not schooled in our science. Pharmacists must be the driving force to find answers to the complexity of issues that we face; Medicare out-patient prescription drug coverage, drug product shortages, medication errors in pharmacy practice, bio-terrorism,

privacy rules, new payment formulas, work place stress and work-loads, to name of few. Pharmacists need to educate the policy makers on what needs to be done. If elected Trustee, I would work with the membership to help assure that pharmacists are defining the profession.

I am currently serving as Speaker of the House of Delegates and a member of the Resolutions Committee. Previously, I served as Vice-Speaker. I regularly attend the Board of Trustee meetings and participate in Legislative Day. I am a preceptor for the University of Maryland School of Pharmacy Experiential Learning Program and an active member of the Eastern Shore Pharmaceutical Society and APhA.

What a proud history MPhA has as it celebrates 120 years of excellence in pharmacy! What an exciting time for MPhA with the mission to ensure the future of the Kelly Building and the museum and library! It would be an honor and a privilege to serve as Trustee; for advancing the expectations the members have for MPhA and the profession.

Position: Trustee Seat #2
Abigail Lagman Strawberry, R.Ph.

If elected to this position, I will do my best to represent the Maryland Pharmacists Association, the profession of pharmacy and you—the pharmacists of the state of Maryland.

I have been practicing as a hospital pharmacist for 8 years and as a retail community pharmacist for the past year. These experiences have shown me the diversity of our profession.

We are in a dynamic profession which is constantly changing. We must take a proactive role in our profession in order for us to provide the pharmaceutical care our

patients and customers need and deserve.

As a Trustee, I will be in the forefront on promoting our profession. I will be your voice in the association by actively participating in meetings and committees. I have the work-ethic, dedication, and leadership to help our association make a positive impact on pharmacy and healthcare.

MPhA has given me a great deal in my short pharmacy career as a student and pharmacist. It would be an honor to be elected to the MPhA Board of Trustees. I look forward to working with MPhA in promoting our profession of pharmacy.

Position: Trustee Seat #3
Dennis Klein

4 Romney Court
Owings Mills, MD 21117

I would like to thank Paul Holly, chairman and the members of the Nominating Committee for considering me to represent the Pharmacists of Maryland as a member of the Board of Trustees. I have practiced as a Pharmacist in Maryland my entire career and have been active, both in our pharmacists association and other professional areas. I have served as a voting member of the MPhA's House of Delegates representing AZO Pharmaceutical Fraternity for many years so I know the workings of the MPhA.

Presently I am a community pharmacist in Owings Mills. I serve as a Clinical Instructor for Shenandoah School of Pharmacy and a Clinical Assistant Professor at the University of Maryland School of Pharmacy.

As mentioned before I am very active in AZO. I have served as President of the local chapter, held all the other local elected offices plus several National positions. I am presently on their Executive Board. I have chaired the Fritz Berman Memorial Seminar for 27 years.

Currently, I also am a member of the Board of Pharmacy's Task force

on Supportive Personnel and was on the committee for Administration of Drugs and The Future of Pharmacy.

I am looking forward to serving the Members of the Maryland Pharmacist Association. Thank you for your support.

Position: Trustee Seat #3
Michael Souranis, P.D.

As a community pharmacist and active member of our MPhA, I have had the privilege of serving our association in various capacities including the Legislative Committee, and was honored as the Maryland Distinguished Young Professional of the Year 1997. Through my involvement in our organization, I have had the opportunity to work with and talk to many pharmacists in all practice settings throughout our state pertaining to the day-to-day issues, changes, and concerns that confront our profession. I recognize and continue to share your interest and ideas as to what can we do to promote the betterment of our profession, including compensation for cognitive services to conductive work environments which benefit us and the patients we ultimately serve.

As a candidate for a MPhA trustee, my twenty years of pharmacy experience allows me to work with everyone to make pharmacy in Maryland more strong and appealing and position ourselves to face the issues that lie ahead.

With a diligent commitment to achieving the goals and expectations of MPhA and our profession, I respectfully ask for your support in affording me all possible consideration to serve you as a trustee.



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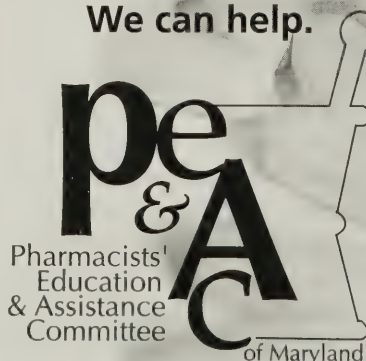


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Please select the candidate you believe will best fulfill the duties of the office by checking the box appearing beside their name.

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Second Vice President

- ☐ Cynthia Boyle, Pharm.D.
- ☐ Joseph Marrocco, P.D.

Treasurer

- ☐ Joseph DeMino, P.D.
-

Please select the candidate you believe will best represent you as a member on the Board of Trustees by checking the box appearing beside their name.

Maryland Pharmacists Association Board of Trustees

Trustee Seat # 1

- ☐ Fred Abramson, P.D.
- ☐ Doug Campbell, P.D.

Trustee Seat # 2

- ☐ Ginger Apyar, P.D.
- ☐ Abigail Lagman Strawberry, R.Ph.

Trustee Seat # 3

- ☐ Dennis Kline, P.D.
- ☐ Mike Souranis, P.D.

When completed, seal and return your self-mail ballot to the Maryland Pharmacists Association, *received by Friday, April 26, 2002*. For questions, please call MPhA at 800-833-7587.

**Only official ballots from the “Maryland Pharmacist”
journal will be accepted—no photocopies.**

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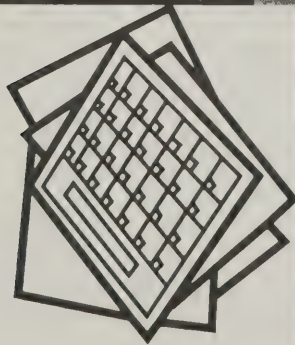
2002 Maryland Leadership Elections

Maryland Pharmacists Association

650 W. Lombard Street

Baltimore, MD 21201-1572

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June 2002 MPhA 120th Annual Convention

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Crab Feast
Berlin Fire Hall
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Show/Job Fair
Awards Banquet

16 17 18 19 20 21 22

23 24 25 26 27 28 29

30



Recognizing Pharmacy Excellence The 2002 MPhA Awards

Each year, the Maryland Pharmacists Association recognizes professional excellence through a series of awards. To nominate a pharmacist for one of the awards described below, complete the Official Award Nomination Form. The forms should be submitted to: Award Nominations, c/o Maryland Pharmacists Association, 650 West Lombard Street, Baltimore, Maryland 21201-1572.

All nominations will be reviewed by the Past Presidents Council who is responsible for selecting the award recipients. The decision of the Council is final. Award recipients will be notified in advance of the award's presentation at the 120th Annual MPhA Convention.

For consideration, all nominations must be received no later than *Friday, April 12, 2002*.

- **Pharmacists Mutual Distinguished Young Pharmacist Award**
Awarded to a pharmacist who graduated within the past ten years and has made a significant contribution to the profession through service to a local, state or national pharmacy organization. *Who is Eligible:* Any MPhA pharmacist member who graduated from pharmacy school in 1993 or after.
- **Maryland Pharmacists Association Honorary President**
An honorary position on the Board of Trustees given to a person, not necessarily a pharmacist, who has worked for the MPhA or Maryland Pharmacy over a long period of time. *Who is Eligible:* Any long standing contributor to the profession or the Association.
- **Seidman Distinguished Achievement Award**
Created to honor the major impact on the pharmacy profession by Henry Seidman, this award is presented for outstanding service by a Maryland pharmacist to the pharmacy profession during *either* the past year or over a period of years. *Who is Eligible:* Any MPhA pharmacist member who meets the criteria of the award.
- **Wyeth-Ayerst Bowl of Hygeia Award**
The Bowl of Hygeia recognizes a pharmacist who has performed outstanding services to the community in any area, with a particular emphasis on non-pharmacy contributions. *Who is Eligible:* Any MPhA member pharmacist who has not already received the Bowl of Hygeia.
- **Elan Innovative Practice Award**
Established in 1993, this award aims to recognize forward-thinking pharmacists who have expanded their practices into new areas. Any practicing pharmacist member within the geographic area who has demonstrated innovative pharmacy practice resulting in improved patient care. *Who is Eligible:* Any MPhA pharmacist member who meets the criteria of the award.

Maryland Pharmacists Association

Award Nomination Form

To nominate a Maryland pharmacist for one of MPhA's annual "Recognizing Pharmacy Excellence" awards, this form must be completed and returned to the Maryland Pharmacists Association no later than **Friday, April 12, 2002**. All nominations will be held in strictest confidence by the MPhA Past Presidents Council, which is responsible for selecting the award recipients. The decision of the Council is final. Award recipients will be notified in advance of the presentation of the award.

Please consider the following nominee for:

☐ **Pharmacist Mutual Distinguished Young Pharmacist Award**

Nominee _____
Home Address _____
City/State/Zip _____
Current Place of Employment/Practice _____
Telephone _____
Work Phone _____
Name of Nominator _____
Nominator's Phone _____

☐ **Seidman Distinguished Achievement Award**

Nominee _____
Home Address _____
City/State/Zip _____
Current Place of Employment/Practice _____
Telephone _____
Work Phone _____
Name of Nominator _____
Nominator's Phone _____

☐ **Elan Innovative Practice Award**

Nominee _____
Home Address _____
City/State/Zip _____
Current Place of Employment/Practice _____
Telephone _____
Work Phone _____
Name of Nominator _____
Nominator's Phone _____

☐ **Wyeth-Ayerst Bowl of Hygiea**

Nominee _____
Home Address _____
City/State/Zip _____
Current Place of Employment/Practice _____
Telephone _____
Work Phone _____
Name of Nominator _____
Nominator's Phone _____

☐ **MPhA Honorary President**

Nominee _____
Home Address _____
City/State/Zip _____
Current Place of Employment/Practice _____
Telephone _____
Work Phone _____
Name of Nominator _____
Nominator's Phone _____

Attach a current resume or curriculum vitae for the nominee that shows their professional and personal achievements. This information is essential for the Past Presidents Council to make its decisions as to which candidates will be recipients of the "Recognizing Pharmacy Excellence" awards. In addition, the nominator should attach a brief letter explaining why the nominee is worthy of receiving this award.

Return the completed form to:

Awards Nominations
c/o Maryland Pharmacists Association
650 W. Lombard Street
Baltimore, MD 21201-1572

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2002 Awards Nominations
Maryland Pharmacists Association
650 W. Lombard Street
Baltimore, MD 21201-1572

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AND THE LAW

By Kenneth R. Baker, B.S.Pharm., J.D.

This series, **Pharmacy and the Law**, is presented by Pharmacists Mutual Insurance Company and your State Pharmacy Association through Pharmacy Marketing Group, Inc. a company dedicated to providing quality products and services to the pharmacy community.

"I HAVE BEEN SERVED WITH A SUBPOENA – NOW WHAT DO I DO?"

At about 4 pm, Frank received an envelope marked "Certified". Inside was an official looking document addressed to him as "Custodian of Records" for his pharmacy. At the top was the identification of the Circuit Court for the district in which the pharmacy is located. The next line read: "Subpoena" and underneath that: "Order to Appear and/or Produce Documents", and further down the page, after naming the plaintiff [wife] and the defendant [husband] in the legal action, were the ominous words:

- ❑ "YOU ARE HEREBY COMMANDED, that setting aside all manner of excuse and delay, you be and appear at Family Court Building, Room ____ at 9 AM on Friday, the ____ day of _____, 2001.
- ❑ To produce the following: Any and all records of prescriptions filled in the name of [defendant/husband] from _____ to _____.

At the bottom of the subpoena were the name, telephone number and address of the attorney for the wife who had prepared the subpoena and caused it to be sent to Frank. The name of the court clerk was stamped on the subpoena along with the court seal.

Frank groaned when he considered how difficult and expensive it would be to hire a replacement pharmacist so that he could attend the hearing. The last time he tried to find a pharmacist to work one day so he could take a vacation day it took almost three weeks to locate someone willing and able to work. Paying someone to help out while

Frank went fishing was one thing, but to attend his customers' divorce hearing seemed beyond duty.

Frank called the attorney for the wife listed on the bottom of the subpoena and explained to her his problem and reluctance. The wife's attorney was very sympathetic. She told Frank that he did not need to take off work or hire a replacement or even attend the hearing. All Frank needed to do, according to the lawyer, was send her a copy of the requested prescription records and she would introduce them into court without his testimony. Frank was relieved. He printed off a copy of the husband's prescription record, sent it to the lawyer and quickly forgot about the entire incident.

Six months later Frank was reminded of the incident with a letter from the husband's attorney, which read, in part:

Please be advised that I represent [the husband] in his claims against [the pharmacy] arising out of an unauthorized disclosure of confidential medical records.

Our preliminary investigation indicates that your facility released prescription records pursuant to [a subpoena], without a medical authorization, and in violation of my client's right to privacy. . . . You were never directed by . . . my client to release said records. The records were produced . . . in violation of [state law].¹

Please contact the undersigned if you wish to discuss settlement of our claims. If we fail to hear from you I will file suit on behalf of my client . . .

Frank was surprised. He thought the subpoena was an order from the Court. Frank did not understand that in most jurisdictions a subpoena is prepared by one of the lawyers, without consulting with anyone. The subpoena is not an order to share the material requested with the lawyers, but a direction to bring the records to the place where a deposition or, as in this case, the hearing is to be held.

Had Frank done what the subpoena directed, rather than what the wife's attorney suggested, he would have printed out the prescription record, made copies of the prescriptions, and showed up at the Court for the scheduled hearing. Then, Frank would NOT have handed the records to anyone. Instead, something approximating the following exchange would have happened:

Wife's Attorney: *Frank, did you bring with you the records subpoenaed by me on behalf of my client?¹.)*

Frank: *Yes, I did. They are right here.*

Wife's Attorney: *Please hand the records over to me.*

Frank: *I cannot do so without a release from my patient or an Order from the Court.*

Husband's Attorney: *Your Honor, my client does not release his rights to confidentiality and I object to the production and disclosure of these records.*

The Court would then make the decision as to whether the records should be ordered released over the objection of the husband. Regardless of how the Court ruled, Frank would have had the protection of acting pursuant to an order of the Court.

The safer course of conduct for Frank when he received the subpoena would have been to call the patient whose records were being requested. If

Frank had received a release from the patient he could have forwarded the records to whomever the patient indicated in the release. There are times when the attorneys for the parties have already reached an agreement as to the mutual release of records and will give permission to send the records to both attorneys.

However, it is possible that the patient may object to the release of his records to his soon to be ex-wife. In that event Frank could have suggested that the husband's attorney contact him and, as an agent for the husband/patient, give him directions. Had the lawyer for the husband been aware of the subpoena prior to Frank sending them to the wife's lawyer, he could have objected to the Court and have asked the Court to dismiss (or quash) the subpoena.

All else failing, Frank could have called his own attorney and explained the problem and expense of trying to find a relief pharmacist. Frank's attorney may have been able to quash the subpoena until the attorneys could agree or the Court issued its order. Frank's attorney could also have been able to have another person at the pharmacy accepted as "keeper of the records" and satisfy the subpoena without Frank or a pharmacist appearing.

Frank is not the first pharmacist who faced the question of how to respond to a subpoena. Nor was Frank the first to receive a threat of lawsuit arising out of the method that the pharmacy used to react to such a subpoena. The method Rite Aid used in one of its Rhode Island pharmacies resulted in an action for damages against Rite Aid in the case of Washburn v. Rite Aid Corp.². As in Frank's case, the Washburns were in the process of a contested divorce when Mr. Washburn's attorney subpoenaed Mrs. Washburn's prescription records from Rite Aid. Also, as in Frank's case, rather than bring the requested records to the deposition as stated in the subpoena, copies of the records were mailed directly to Mr. Washburn's attorney. The Court in the Rite Aid case concluded there was an unauthorized release of records and damages could be sought against the pharmacy.

Pharmacists may think, as did Frank, that a subpoena is a Court order. This misconception has been recognized by the Courts. In State ex rel. Crowden v. Dandurand³, the Court commented:

. . . Custodians often mail the records to requesting counsel instead of bringing them to the deposition as required by the

¹ The purpose of this article is not to debate the attorney's opinions as to the law of pharmacist confidentiality in his particular state, but to address possible responses to a subpoena.

subpoena. A medical provider that reveals privileged information by mailing records in lieu of attending a deposition may be sued in tort for breach of the fiduciary duty of confidentiality. [citations omitted]

Pharmacists must understand that a subpoena must be obeyed. But, it must be read exactly. If a pharmacist receives a subpoena for prescription records, the pharmacist should turn to the expert and ask his or her attorney how to respond. The pharmacist cannot rely on advice given by one of the attorneys for the parties. The pharmacist should not just give the records to the person requesting them unless a release signed by the

patient or an order signed by the Judge is attached. So, when you are served with a subpoena, what are you going to do?

© Kenneth R. Baker is Vice President, General Counsel at Pharmacists Mutual Insurance Companies.

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with the policies and procedures of their employers and insurance companies, and act accordingly.

² 695 A.2d 495 (R.I. 1997)

³ 970 S.W.2d 340 (MO. En Banc. 1998)



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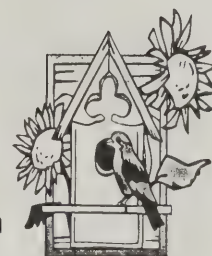
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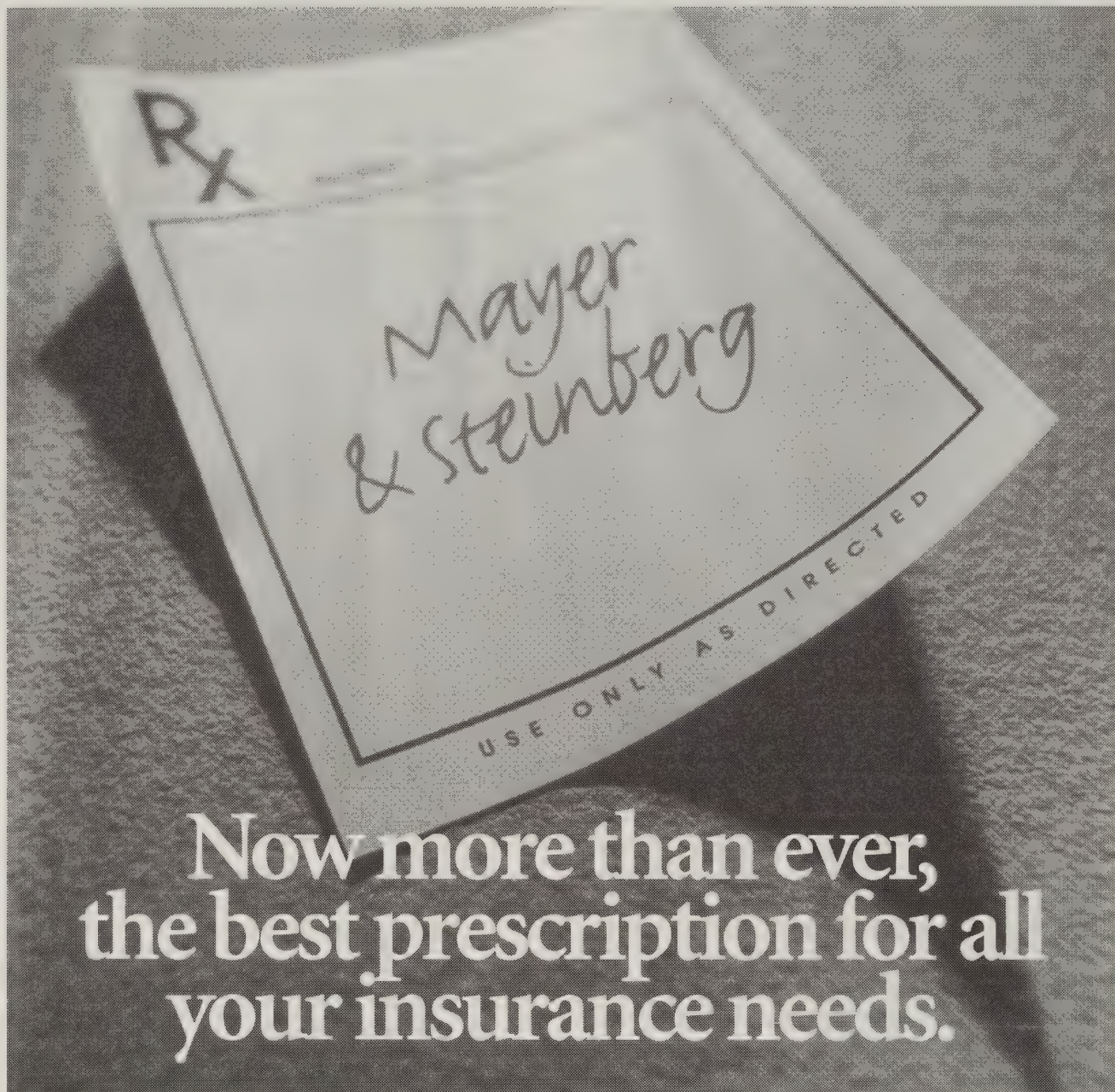
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Medicaid Prescriptions

Current answers to questions most frequently asked by Pharmacists

Does Medicaid allow phone-in prescriptions?

No, phone-in prescriptions are not allowed for fee-for-service Medicaid prescriptions. (COMAR 10.09.03.04A) However, if a recipient is in a Managed Care Organization (MCO) and the prescription is being paid by the MCO, the rules of the MCO would apply.

Are faxed prescriptions allowed?

Yes, an original written order signed by the prescriber faxed directly from the prescriber to the pharmacy provider in accordance with applicable federal and state laws is acceptable. (COMAR 10.09.03.01B(26))

Does a Medicaid prescription still have to be written on a special form?

No, the prescription blank of the prescriber is acceptable as long as the required information is on the prescription and it is signed by the prescriber. Special Medicaid prescription forms were discontinued several years ago.

How long can a Medicaid prescription be filled after it was written?

Medicaid prescriptions can be filled up to ten days from the date prescribed. (COMAR 10.09.03.05A(3)) If the prescription is over ten days old, the pharmacist can call the physician and verify that the prescription should still be dispensed. If so, the pharmacist can change the date prescribed to the date that the physician verified the prescription. The pharmacist should note this on the prescription along with the date and the pharmacist's initials.

What drugs are covered under Medicaid?

Maryland Medicaid covers legend drugs, enteric aspirin for arthritis, ferrous sulfate, chewable vitamins for children under 12, insulin, syringes and contraceptives. COMAR 10.09.03.04

What is not covered under Medicaid?

Drugs rated as less than effective by the Food and Drug Administration (FDA), fertility drugs, weight control drugs (CNS stimulants), cosmetics, and drugs manufactured by a company that did not sign federal rebate agreement are not covered under Medicaid. COMAR 10.09.03.05A

Does Medicaid pay for diabetic testing and monitoring supplies and spacers?

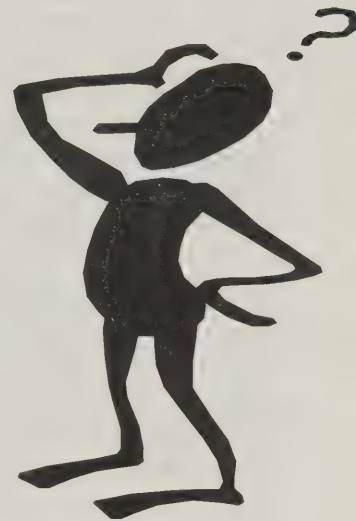
Yes, BUT NOT through the pharmacy Program. These are covered through supply program. The pharmacy must be a provider of supplies and the claim must be submitted on a HCFA 1500 form. (COMAR 10.09.12.04)

What is covered under the Maryland Pharmacy Assistance Program (MPAP)? By law anti-infectives and medications to treat chronic maintenance conditions are covered. The law requires that covered medications be specified in regulations. Some drugs are covered for specific conditions only (COMAR 10.45.02.04).

How many days supply can be dispensed at a time?

If the drug is a maintenance drug, 100 days supply can be dispensed at a time if the prescriber writes for that amount. For patients stabilized on medications, the Program encourages physicians to prescribe a 100 days supply at a time. Pharmacists are not authorized to cut these prescriptions. The list of maintenance drugs consists of the American Hospital Formulary Service (AHFS) therapeutic categories listed below:

- (i) Cardiac drugs (24:04);
- (ii) Hypotensive agents (24:08);
- (iii) Vasodilating agents (24:12);
- (iv) Replacement solutions (40:12) (potassium supplements only);
- (v) Diuretics (40:28);



- (vi) Insulins (68:20.08);
- (vii) Sulfonylureas (68:20.20);
- (viii) Thyroid agents (68:36.04);
- (ix) Vitamins (88:00) (Note: only legend drugs are covered);
- (x) Hydantoins (28:12.12) (phenytoin and phenytoin sodium only);
- (xi) Sodium fluoride (92:00);
- (xii) Iron preparations, oral (20.04.04) (oral products in which ferrous sulfate is the only active ingredient and chewable tablets of any ferrous salt when combined with vitamin C, multivitamins, multivitamins and minerals, or other minerals in the formulation). (COMAR 10.09.03.05C(3)(c))

Prescriptions for drugs not considered maintenance are limited to less than 34 days supply at a time.

Each original signed prescription is good for up to a 100 days supply or 2 refills whichever comes first. A prescription for birth control pills is good for up to 6 months or 2 refills. (COMAR 10.09.03.05C(2)).

What is the co-pay and can it be waived?

The co-pay for Medicaid is \$1 per prescription. Recipients in managed care, pregnant, under 21 years of age, in a nursing home, and prescriptions for family planning are exempt from co-pay. Pharmacists cannot refuse to fill prescriptions because of the recipients' inability to pay the co-pay. Recipients are still liable for the co-pay. (COMAR 10.09.03.05C(6)) There is a \$5 cop-pay for Pharmacy Assistance prescriptions. The pharmacy can waive the co-pay if it wants but cannot charge the Program more to recover cost.

How long must the pharmacy keep records on file for Medical Assistance?

Records must be kept for 6 years. (COMAR 10.09.03.03E)

What is the Medicaid Reimbursement rate?

Medicaid pays the lesser of the pharmacy's usual and customary charge or the calculated reimbursement rate. The reimbursement rate takes into consideration a \$4.21 retail dispensing fee and federal and State generic rates if applicable. The estimated acquisition cost (EAC) for a particular product is the lowest of wholesale acquisition cost plus 10% (WAC + 10%), Distributor's price plus 10%, Direct price + 10% and Average wholesaler's price minus 10% (AWP – 10%). Pharmacies must charge the Program the usual and customary charge that a cash-paying customer would be charged, including senior citizen discounts for similar prescriptions. (COMAR 10.09.03.07)

How are the generic rates determined?

If there is a generic available that can be legally substituted in Maryland, the pharmacist should dispense the generic. The program limits payment to the generic rate unless the doctor specifies brand medically necessary and the reason a generic is not medically appropriate. The ingredient cost for a generic is determined by obtaining the prices from two wholesalers. The lowest priced product from each wholesaler is determined. The generic rate or interchangeable drug cost (IDC) is the higher of these two lowest prices. The federal generic upper limit (FGUL) put out by the Health Care Financing Administration (HCFA) is also considered and the Program uses the lowest of the IDC, FGUL and EAC. All drugs that can be legally substituted in Maryland without calling the physician are assigned an IDC if the generic is available from the wholesaler. (COMAR 10.09.03.01B(12) & (18))

Does the Medical Assistance Program require credits for unused medication?

Yes, if a recipient fails to pick up a prescription, the Pharmacy must credit the Program for the prescription to prevent an overpayment by the Program. (COMAR 10.09.03.08B)

Unused unit dose medication that can be legally returned to stock dispensed to a nursing home recipient must be credited within 60 days of payment by the Program. (COMAR 10.09.03.05C(10)(b))

Provided by the Department of Health and Mental Hygiene

Continuing Education for Pharmacists

Volume XIX, No. 11

Patient Counseling: Management of Sore Throat

Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology and
Toxicology
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph.,
Pharm.D.
Professor Emeritus
University of Cincinnati
Cincinnati, Ohio

Goal. The goals of this lesson are to discuss the meaning of sore throat in terms of what causes it and what it may signify, describe how it is treated, and provide information for pharmacists to use when counseling patients on sore throat.

Objectives. At the conclusion of this lesson, successful participants should be able to:

1. exhibit knowledge of the common causes of sore throat;
2. differentiate between clinical manifestations of sore throat associated with infectious etiology and those caused by non-infectious stimuli;
3. select drug product ingredients to treat sore throat, describe

*This lesson is provided by an
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their relevant pharmacologic principles and therapeutic applications, and cite advantages and disadvantages of each; and

4. demonstrate an understanding of how to counsel patients on drugs reviewed to treat sore throat to assure maximum benefit.

It is estimated that approximately 12 percent of Americans experience a sore throat every two months. Many more complain of two or more sore throat experiences each year. The medical literature states that 15 million people in the U.S. consult a physician each year because of sore throat. A symptom of irritated pharyngeal (throat) tissues, the term *sore throat* usually denotes pain or discomfort, particularly on swallowing. Sore throat may also describe minor irritation of various tissues of the oral cavity or the nasopharynx. Its causes are numerous and varied (Table 1).

Most sore throat afflictions are benign and self-limiting, not requiring medical intervention. A sore throat is often the earliest warning sign of the common cold and influenza, but it can exist independently as the result of other, much more morbid causes. Viral disease such as measles, chickenpox and poliomyelitis, and bacterial infection including diphtheria and oral gonorrhea often begin with the symptom of sore

throat, and the pain may not be particularly severe in the early stages. Streptococcal pharyngitis (i.e., *strep throat*) is a relatively common infection in children. Aplastic anemia, agranulocytosis and acute leukemia may manifest initially as a sore throat. Sore throat is a warning sign of impending blood disorders caused by drugs such as carbamazepine. All of this leaves the condition wide open to potential misinterpretation as to the actual cause, severity and mode of proper treatment.

The problem is even more complicated. Patients' unique descriptions of sore throat may convey many individualistic and very subjective impressions and responses to pain. It is often described as mild, minor or severe, terms that convey a wide variety of

Table 1
**A Partial Listing of Causes of
Sore Throat**

- Smoking; smokeless tobacco products
- Hot or irritating foods or drinks
- Air pollution; noxious gases
- Upper respiratory infections; viral, bacterial and fungal
- Chronic coughing
- Mucus accumulation
- Voice straining
- Sinus drainage
- Allergic rhinitis
- Mouth breathing
- Throat surgery
- Swallowing traumatic objects (e.g., glass, sharp pieces of bone)
- Medications
- Excessive use of nose drops and/or sprays
- Gastroesophageal reflux disease
- Aplastic anemia
- Agranulocytosis
- Acute leukemia

Table 2
Conditions Present With
Sore Throat That Necessitate
Visiting a Physician

- Breathing difficulty
- Fever 102°F or above
- Bloody sputum
- Skin rash
- Dark urine
- Excessive nausea and/or vomiting
- Light headedness
- Fainting
- Chest pain
- Wheezing
- Stiff neck
- Tender gland area in the neck
- Severe headache
- Visible lump in mouth or throat
- Sore throat seems more severe than usual
- No improvement after 3 days of rest and treatment

intensity to both sufferer and health care provider. Sore throat, especially one that persists beyond two days, should not be ignored. It may signal a serious condition that demands immediate medical attention.

Differentiating Serious from Non-Serious Sore Throat Conditions

Most sore throat conditions are self-limiting and will heal on their own within a day or two. Some, though, require prompt medical attention, especially if the person is an infant or elderly adult. A physician should check any person with a sore throat who also has one or more of the symptoms listed in Table 2.

Product Dosage Forms

Most sore throat conditions can be treated effectively with products applied directly to affected tissues in the form of mouthwashes, gargles, sprays and lozenges. Except for lozenges, the duration of contact between solubilized drug in solution and irritated pharyngeal tissues is relatively brief. Liquid preparations mix quickly with saliva and are diluted, then may be swallowed or expectorated. Lozenges provide more

prolonged contact between drug and tissues; as long as the lozenge remains localized in the area, active ingredients bathe irritated tissues. As a general rule, lozenges usually provide more effective analgesia than liquids.

Lozenges. Described as circular or discoid-shaped, solid, oral dosage forms, lozenges (troches) were employed as a medical dosage form as early as 1500 B.C. Lozenges are produced by cutting, punching or molding a flavored mass consisting of sugar, gums or bases of fruits, and mucilage, into which active therapeutic ingredients are incorporated. Lozenges are intended to be sucked slowly without biting, thereby releasing their ingredients into the mouth and throat gradually as they dissolve, where they act directly on irritated tissues.

A number of variables may alter their efficacy, and it is difficult to assess their therapeutic effectiveness objectively. For example, the rate of dissolution, taste, odor, appearance, stability, consistency and size are important considerations. The quantity, pH and viscosity of saliva, and size and area of the mouth and throat are other variables relevant to determining the overall activity of lozenges and a person's response to them.

Once a lozenge dissolves and the drug is washed away by saliva or by drinking fluids, its effect may dissipate. For lozenges to be maximally effective, therefore, they must be used frequently, usually in succession. Lozenges that deliver only mild demulcents or soothing agents may need to be replaced quickly, perhaps within 10-15 minutes after one lozenge dissolves to maintain a soothing effect. Those that contain active pharmacologic ingredients are restricted in how often they can be used. Most ingredients in lozenges are ultimately swallowed and the drug components can be absorbed from the stomach or small intestine. The frequency of use can be determined by the product's instructions.

Lozenges may contain one or

more active ingredients. Most contain a local anesthetic which provides temporary relief from throat pain by reducing the sensitivity of sensory nerve fibers. Some products contain aromatic flavors or substances that stimulate secretion of excess saliva to help soothe irritated tissues. If these substances are volatile, their vapor may also help reduce pain. For example, menthol creates a local anesthetic action by stimulating cold receptors to mask pain temporarily.

Demulcents act as protectants by coating irritated or inflamed mucous membranes. Astringents coagulate topical protein thereby relieving symptoms, so they are also protectants. Debriding agents and expectorants help remove phlegm, mucus and debris which can irritate inflamed tissues, and thereby relieve pain and discomfort. Decongestants shrink swollen mucous membranes and relieve congestion, both of which stimulate pain receptors. They may also retard absorption of topical anesthetics and thereby prolong pain relief.

Gargles and Mouthwashes.

Gargles are aqueous-based liquids that are usually flavored or medicated, or both. They are intended to cleanse the posterior portion of the oral cavity and aid in expelling mucus from the throat. Mouthwashes (mouthrinses) also may or may not be medicated and/or flavored. Alcohol, if present, usually serves as a solvent for one or more ingredients. Their function is to bathe the oral tissues. The three terms, *gargles*, *mouthwashes* and *mouthrinses* are often stated interchangeably and refer to how the solutions are used within the oral cavity, rather than to specific therapeutic benefits.

The therapeutic value of gargling as a means to deliver drugs to pharyngeal tissues is controversial. With gargling, the tongue rises to keep the fluid localized to specific tissues. Gargle solutions reach the anterior tissues adequately, but not the posterior pharyngeal wall. Therefore, there is little or no direct

contact between drug and irritated pharyngeal surface. The airstream produced while gargling may help expel mucus. This may be aided by drinking a small amount of water immediately before gargling to moisten the pharyngeal tissues. Medication in gargles does reach the throat if the solution is swallowed.

Product Ingredients

Local Anesthetics. Local anesthetics are the mainstay active ingredients for treating sore throat. They block the generation and conduction of nerve impulses along neurons when applied locally to mucous membranes in appropriate concentrations. Their action is completely reversible, with no convincing evidence to suggest they cause structural damage to nerve fibers or cells.

Benzocaine (ethyl-p-aminobenzoate) is a widely used topical anesthetic. Contained in lozenges in strengths of 0.1 to 0.5 percent, these concentrations alleviate pain, but do not cause a loss of reflex swallowing activity. Systemic absorption of the small amount of swallowed drug is so slight that blood levels are barely detectable.

There are reports in the medical literature that benzocaine is an allergic sensitizer. Benzocaine can combine with tissue protein to initiate reactions mediated by IgE antibodies which then release histamine from its storage sites in susceptible individuals to induce sensitivity reactions. However, confirmed allergic reactions to the local anesthetic are rare. A patient who is hypersensitive to benzocaine can safely use other agents with a different chemical structure (e.g., dyclonine) without fear of cross-reaction. Nonetheless, benzocaine should not be applied for prolonged periods of time, to minimize the possibility of serious allergic reactions.

Dyclonine is a local anesthetic with both rapid onset and short duration of action comparable to

that of procaine. Dyclonine is used in doses of 1.2mg, 2mg, and 3mg per lozenge, and 0.5 to 1 percent in solution.

In an evaluation to compare its effectiveness with other local anesthetics, dyclonine ranked fourth, after dibucaine, cocaine and tetracaine. A 1 percent solution produced a duration of action of anesthesia of 26 minutes, preceded by a latent period of two to three minutes. This compared with a duration of effect of approximately four minutes for 20 percent benzocaine solution, three minutes for 10 percent benzyl alcohol solution and 1.5 minutes for 3.5 percent menthol solution. Used as a rinse or gargle, dyclonine may relieve sore throat pain for up to an hour. When used in the form of lozenges, it may relieve pain due to sore throat for several hours if kept in the mouth long enough.

Hypersensitivity reactions occur rarely. Dyclonine may produce slight irritation or stinging. It has a low order of toxicity and is one of the safest topical anesthetics with an incidence of adverse effects, including hypersensitivity, less than that of benzocaine.

Benzyl alcohol, in concentrations of 1 to 3 percent, is safe, but less effective than benzocaine or dyclonine as a topical anesthetic. After absorption, it is converted to hippuric acid by hepatic metabolism and eliminated in the urine. Benzyl alcohol possesses bacteriostatic activity against a limited number of microbial species. While used as a preservative, no claims can be made that it is an effective antiseptic.

Eucalyptol boasts a long history of use as a topical antiseptic with mild anesthetic activity. It is safe; however, its effectiveness has not yet been confirmed in controlled clinical trials. Eucalyptol is used in some OTC products that are promoted to soothe sore throat because it imparts a characteristic medicinal odor and flavor and therefore, by association, beneficial activity. However, it is not considered to be a therapeutically-active ingredient.

Hexylresorcinol has equal

anesthetic potency to phenol, but is less caustic. Its duration of topical anesthetic action in an aqueous solution as a rinse or gargle is stated to be 5 to 10 minutes.

Menthol is used as a flavor in candy, chewing gums and other confections, in cigarettes and in inhalant preparations for the nose and throat. When used with camphor and applied topically to the chest, menthol has proven effectiveness in alleviating cough and congested nose (e.g., Vicks VapoRub). In mouthwashes and gargles, like eucalyptol, menthol adds a characteristic medicinal odor that can provide significant placebo activity.

Phenol was first described by Lister in the 18th century. Aqueous solutions between 0.2 and 1 percent are bacteriostatic; above that concentration, phenol solutions are bactericidal. Phenol is believed to exert bactericidal action by denaturing protein.

Phenol is an anesthetic and antimicrobial at concentrations used in OTC sore throat products. Phenol penetrates sensory nerve endings and exerts local anesthetic action that is qualitatively similar to benzocaine. One product that contains phenol, 1.4 percent, instructs users to spray the throat, then swallow. The small quantity of phenol ingested in this manner is well below the reported 2-gram oral lethal dose. Aqueous solutions above 1.5 percent are caustic and may cause tissue necrosis if used excessively.

Quaternary Ammonium Compounds

Cetylpyridinium chloride is the only quaternary ammonium compound used in throat lozenges at this time. Others are contained in various mouthwash products. Quaternary ammonium compounds reduce the bacterial count in the mouth significantly after rinsing. Their role in the therapy of sore throat has not yet been proven. Low concentrations of antimicrobials

Table 3**Patient Information****General Information:**

- Your throat may feel better if you gargle with warm salt water (1/4 teaspoon of salt to one-half glass of warm water); or drink cold liquids or eat frozen confections. Avoid citrus products like orange juice that may add to discomfort.
- Do not smoke. Smoking irritates and dries the mucous membranes that line your throat.
- Do not use this product longer than two days or give to children under three years of age unless the package instructions indicate otherwise, or the product is being used under the supervision of a doctor.
- Discontinue use of this product and consult your doctor if irritation persists or increases, or a rash appears on the skin.
- Keep this and all medicines out of the reach of children.

For Lozenges:

- Let this product dissolve in your mouth slowly. Do not chew the lozenge or bite into it. Swallow your saliva.

For Gargles or Mouthwash Products:

- Avoid swallowing this product, unless instructed to do so by your doctor or pharmacist.
- These products have a high degree of safety. However, if they contain alcohol, severe toxicity can result when a child drinks the solution. Be sure to keep such products out of children's reach.

For Sprays:

- Spray this product far back into your mouth and swallow.
- Apply this product according to instructions. You can also apply it several times each day with spitting out, rather than swallowing your saliva.

may alter the natural flora in the mouth, which encourages overgrowth of resistant bacteria and fungi, such as *Candida* species.

While cetylpyridinium is antibacterial and can be used for oral hygiene, it has only limited local anesthetic action. Therefore, for self-

treatable sore throat, a product containing a local anesthetic, rather than a quaternary ammonium compound, may provide greater pain relief.

Additional Considerations

Orally ingested aspirin, acetaminophen, ibuprofen or other OTC NSAIDs may help combat throat discomfort. Analgesic doses can be taken to supplement the action of lozenges and/or other topically active products. The usual precautions prevail for these products when used to treat sore throat pain, as when they are used for any other type of pain.

Besides the wide assortment of sore throat remedies available without prescription, patients can be instructed to suck hard candy between use of lozenges and/or mouthwashes. This stimulates the flow of saliva that will help soothe irritated mucous membranes.

A solution of one teaspoonful of table salt in a pint of warm water, gargled as needed, may help also. An alternative remedy calls for one tablespoonful of baking soda, mixed in a large glass of water. The solution should be sipped slowly throughout the day.

Advising Patients on Sore Throat

Individuals seeking relief of sore throat symptoms should be questioned about the nature and degree of discomfort. Unfortunately, there is no way to identify the cause of a sore throat rapidly and reliably without asking these questions. It should be remembered that an individual's description of his condition is subjective and open to misinterpretation.

The individual with sore throat should also be questioned about other symptoms. If throat pain is accompanied by congestion or obstructed breathing, an oral or topical decongestant can be recommended. Cough may be treated with an antitussive and/or expectorant.

Runny nose and eyes, muscle aches and pain, fever and gastrointestinal disturbance may signal that a viral infection is present. Sore throat accompanied by a patchy exudate over the mucosa suggests a streptococcal infection. Patients infected often have a "thick" altered voice. Coughing is usually absent. Such individuals should be advised to consult a physician. Left untreated, streptococcal infections can lead to rheumatic sequelae – rheumatic fever and rheumatic heart disease. Renal damage and even a type of arthritis can also follow untreated streptococcal infections. Information presented in Table 3 may be helpful when counseling patients on management of sore throat.

Patients may ask about the value of antibiotics to treat sore throat pain. Unless the symptom is caused by a bacterium that has been identified, antibiotics should not be employed to treat otherwise uncomplicated sore throat conditions.

For most people with sore throat pain, an OTC product containing a local anesthetic should provide adequate pain relief. If a local anesthetic-containing product is chosen, it should be one that has proven safety and a prolonged duration of action. In addition, one that tastes good would be even better!

Summary

Sore throat is common. Most conditions are not serious in that they are caused by pharyngeal irritation by otherwise non-noxious stimuli. These conditions are relieved, for the most part, by ingredients in products available without prescription.

Continuing Education Quiz

This month's questions are taken from the article on "Patient Counseling: Management of Sore Throat." Circle your answers to the following questions and mail the entire page to Maryland Pharmacist CE, 650 W. Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members \$ 10.00). The completed quiz for this issue must be received by 11/15/04. A continuing education certificate for one and one-half contact hours (0.15 CEUs) will be mailed to you within six to eight weeks. Please type or print clearly. ACPE# 129-144-00-003-H01.

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1. The term sore throat refers to irritation of the:
a. gingival tissue. c. pharyngeal tissue.
b. thorax. d. tonsils.
2. Which of the following dosage forms provides the most prolonged contact between drugs and tissues in the mouth?
a. Gargles
b. Lozenges
c. Mouthwashes
d. Sprays
3. A substance that acts as a protectant by coating irritated or inflamed mucous membranes is a(n):
a. astringent. c. decongestant.
b. debriding agent. d. demulcent.
4. A substance that coagulates topical protein to relieve a sore throat is a(n):
a. astringent. c. decongestant.
b. debriding agent. d. demulcent.
5. A substance that shrinks swollen mucous membranes is a(n):
a. astringent. c. decongestant.
b. debriding agent. d. demulcent.
6. Benzocaine is contained in lozenges in which of the following strengths?
a. 0.01 to 0.05 percent
b. 0.1 to 0.5 percent
c. 1 to 5 percent
d. 5 to 10 percent

7. Which of the following has the lower reported incidence of hypersensitivity reactions?
a. Benzocaine
b. Dyclonine
8. All of the following are classified as local anesthetics EXCEPT:
a. benzyl alcohol.
b. hexylresorcinol.
c. phenol.
d. cetylpyridinium.
9. All of the following points of information are appropriate for counseling patients on the correct use of lozenges EXCEPT:
a. let this medicine dissolve in your mouth slowly.
b. do not chew this medicine.
c. do not swallow your saliva.
d. do not bite the lozenge.
10. Sore throat accompanied by a patchy exudate most likely suggests that the patient has a(n):
a. streptococcal infection.
b. HIV infection.
c. rhinovirus infection.
d. hepatitis infection.

For Your Information...

From: Maryland Department of the Environment



There are legislative requirements in Maryland that are relevant to your industry of retailing or distributing mercury fever thermometers. Among these requirements is the prohibition on the sale and distribution of mercury fever thermometers in Maryland, except by prescription, beginning October 1, 2002. This prohibition does not apply to fever thermometers sold or provided for use in hospitals or other areas where professionals provide medical services. The prohibition also does not apply to digital thermometers containing mercury-added button cell batteries.

The law recognizes that mercury is a serious environmental and public health threat today. Your business plays a key role in protecting future generations by reducing the content of mercury in products and controlling the release of mercury into the environment.

To review the law in its entirety, please visit the Maryland General Assembly web page <http://mlis.state.md.us/2001rs/billfile/HB0075.htm>. For fact sheets and general information on mercury, visit the Maryland Department of Environment's web site at <http://www.mde.state.md.us> or call Regina Rochez, Program Manager, Planning, Recycling and Outreach Program at 410-631-3314.

Richard W. Collins, Director
Waste Management Administration

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Pharmacist Licensure Examination

For the results of the Pharmacist Licensure examination visit the Maryland Board of Pharmacy's website at: www.dhmd.state.md.us/pharmacyboard/pharmlic/0600rost.htm. The results are updated every Friday.



We are Looking

MPhA is looking for original works. If you are a member and have a paper or would like to write an article for an issue of the *Maryland Pharmacist* send your typewritten copy to MPhA, 650 W. Lombard Street, Baltimore, MD 21201-1572 or FAX to 410-727-2253. Please be sure to put your name and phone number on your piece. All copy is subject to approval and space availability.

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MARYLAND

Pharmacist

VOLUME 78 NO. 2

President's Commentary

"The Year in Review"

120th Anniversary

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120th Anniversary

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120th Annual Convention
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The Official Publication of the Maryland Pharmacists Association

President's Commentary 5

"The Year in Review"

Director's Column 7

"Legislative Review"

Information 9

"Two HIPAA Compliance Issues"

The Pharmacist Shortage 11

"Emerging Careers Offer Competition to Traditional Pharmacy Practice"

2002 General Assembly Report 15

Latest Research Unleashes Sleeping Genie 17

"50 Years in the Bottle"

120th Anniversary 25

"Annual Convention Registration Form"

KAVA 27

"Safety is Questioned...Link to possible liver toxicity subject of inquiries"

Continuing Education 33

Patient Counseling: " Glaucoma; Part 1: The Disease"

Advertiser's Index

Giant	20
Mayer & Steinberg	16
McKessonHBOC	4
Medicine Shoppe	32
MPhA Foundation	8, 24
PEAC	12
Pharmacists Mutual	6
PharmaSTAT	26
RPh on the go	32
Safeway	20
Walgreens	10

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The Year in Review

It is hard for me to believe that my term as President is rapidly approaching an end. The year has gone quickly, but certainly not without a great deal of activity, accomplishment, and significant progress for pharmacy in Maryland and MPhA.

As my final address as President of MPhA, I want to begin by extending my extreme thanks and appreciation to:

the membership for allowing me the opportunity to serve as your president,

the officers, board of trustees, committee chairs, and committee members for your tireless commitment and hard work that enabled us to accomplish so much, and

the MPhA staff for your dedication and commitment to the profession and the Association.

I indicated that this has been a year of accomplishment and progress for MPhA and for the profession of pharmacy. We have reported on all activities of the MPhA throughout the year, however, I have the awesome pleasure of outlining the hi-lights of the accomplishments achieved during my term of office:

The formation of the Maryland Pharmacy Coalition (MPC), a monumental effort to stimulate unity within the profession and strengthen the "Voice of Pharmacy".

A 10% growth in membership, the greatest increase in the past decade.

Kick-off of the largest fundraising effort in the history of the Association.

A special 120th anniversary celebration at the Kelly Memorial Building, the Association's headquarters in Baltimore, following the Annual Mid-Year meeting.



Mark Sanford, P.D., President

A very successful 2nd Annual Legislative Day in Annapolis hosted by the MPC and attended by over 100 pharmacists and pharmacy students.

Passage of legislation allowing for collaborative practice/medication management agreements between pharmacists and physicians. Special thanks to George Voxakis for his 6 year effort culminating in a tremendous achievement for Maryland pharmacy.

In response to emergency preparedness planning following the events of 9/11, MPhA is leading the effort to establish gubernatorial authority to enable pharmacists in Maryland to administer medications, including immunizations, in emergency situations.

It is with a sense of tremendous accomplishment that I end my term as President of MPhA, and the experience is one I will treasure. I am confident that MPhA will continue to shape the future of pharmacy in Maryland, and I look forward to working with the future leadership of this Association to achieve new heights for our profession.

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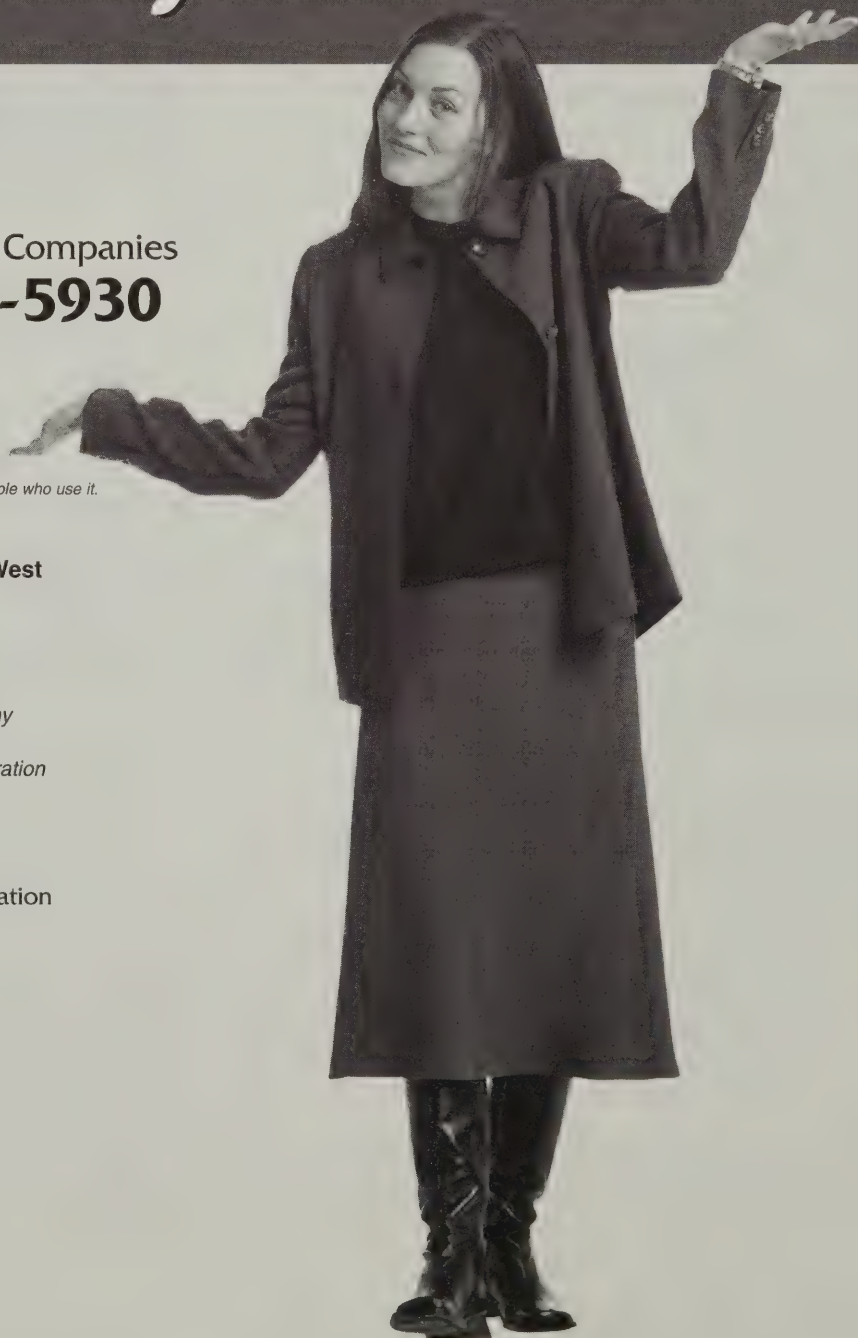
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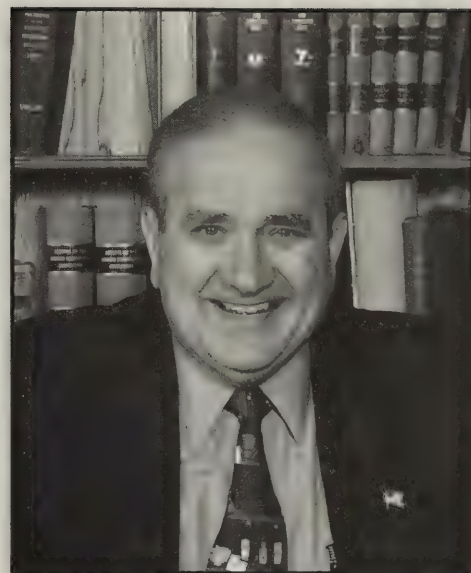


Legislative Review

I have outlined elsewhere in this edition of the journal the status of the major bills affecting pharmacies and pharmacists in the 2002 General Assembly. The results this year were mostly positive even though the problems with budget were overpowering. They reinforced my constant amazement at the workings of the legislature.

- If you had asked me before the start of the 2001 session if the Drug Therapy Management bill (collaborative practice) had a chance to be passed, I would have told you there was very little. This year it passed without a single negative vote. Somehow through the combined efforts of every facet of the profession, we were able to convince the medical society and the General Assembly that the bill was in the best interest of the citizens of Maryland.
- The battle over the budget was an entirely different matter. There were 52 bills that had some impact on pharmacy reimbursement or operations. The largest reduction in drug costs proposed by the Department of Health and Mental Hygiene (DHMH) would have come from an increase in the discount paid to pharmacies from AWP -10% to AWP -13%. Chiefly through the work of the chain lobbyists, this cut was delayed until DHMH reports to the legislature on October 1. However, to avert the reductions, the pharmacy community, through DHMH instituted flexibility in copays, prior authorization, preferred drug lists, increased generic use, increases in refills allowed, and other methods, must be able to show reductions in the Medicaid drug budget. The Senate was convinced that manufacturers should pay supplemental rebates to have their branded medications included in a preferred drug list but the effort died when manufacturers were able to avoid rebates in the House version of the bill.
- The image of pharmacy has been enhanced. As a result of the annual Legislative Day, legislators are more receptive and more knowledgeable. We were recognized and added as a member of task forces or councils on osteoporosis, pain management, and end of life. If the disease state management bill had passed, there would have been a pharmacist on that panel also. All facets of the profession worked well together while acknowledging each other's position.
- CareFirst BlueCross BlueShield's attempted sale to a for-profit company met with stiff opposition from the General Assembly and the public. The publicity seems to have awakened everyone to something we've known; Care First has not acted like a nonprofit created for the public good for a long time. As a result, the legislature decreed the sale must all be in cash, the executives of CareFirst cannot collect \$33 million in bonuses, and the sale must be reviewed by both the insurance commissioner and the General Assembly.

In order to be effective in Annapolis, it is necessary for each pharmacist to maintain a positive image for the profession. This includes our daily interaction with the public. Advocates for pharmacy have found, when talking to or testifying before legislators, that the story we tell is sometimes negated by events or conversations that legislators or their aides find in their personal encounters with pharmacy. Please keep the negativity behind the counter. Our livelihoods depend on it.



Howard Schiff
Executive Director

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Information on Two HIPAA Compliance Issues

1. Business Associate Contracts Required by the Final Privacy Regulation

The final privacy regulation, *Standards for Privacy of Individually Identifiable Health Information*, was created to protect the confidentiality of medical records and other personal health information. The regulation sets standards and requirements to control the flow of protected health information (PHI) throughout the health care system^C including PHI that is used or disclosed by a pharmacist, a pharmacy, or a pharmacy's business associate. On March 27, the Department of Health & Human Services (HHS) released a proposal to modify the privacy regulation. While the proposal does not make any substantive changes to the business associate provisions in the regulation, it is important to note the regulation is not yet final and changes to the business associate provisions could be made when the regulation is finalized.

Compliance Deadline

Providers must comply with the privacy regulation by April 14, 2003. However, as part of its recently proposed modifications to the privacy regulation, HHS has proposed a one-year extension for providers to *revise their existing business contracts*. If the

Administration enacts the proposed changes, providers with existing contracts with business associates will have until April 14, 2004 to revise their contracts and come into compliance with the regulation.

What is a Business Associate?

A "business associate" is a third party that receives or creates protected health information from or on behalf of a pharmacy. Business associates typically provide a service to the pharmacy or provide a service on the pharmacy's behalf. Examples of services a business associate may provide to a pharmacy include consulting, accounting, legal, management, administration, accreditation, and financial services that involve protected health information. Examples of services a business associate may perform on a pharmacy's behalf include claims processing or administration, data analysis, drug utilization review, quality assurance, benefit management, practice management, and billing.

Under the regulation, pharmacy benefit managers (PBMs) are not automatically considered a pharmacy's business associate. Providers must review the services a PBM provides to the pharmacy to determine if the PBM qualifies as a business associate.

Business Associate Contracts

Providers that disclose PHI to a business associate must ensure that the business associate will appropriately safeguard that information. To meet this requirement, a provider must have a written contract with the business associate. The business associate contract

must outline the permitted uses and disclosures of PHI that the business associate is allowed to make. The business associate contract must also include information describing the business associate's responsibilities.

A model business associate contract developed by HHS is available from MPhA. Please note - this model contract is not yet a final regulation, it is part of the recently released proposal to modify the final privacy regulation.

We understand that some pharmacies have begun to receive business associate contracts from PBMs and other third parties they conduct business with. Providers should evaluate these agreements closely particularly because the Administration has proposed modifications to the privacy regulation including a delay in implementing this requirement. While the modifications to the privacy regulation are only *proposed* changes at this point, it is important to note that the regulation is currently in flux. While the proposed modifications do not change the substance of a business associate contract, until the rule is finalized, it is impossible to determine if the business associate contract will comply with the regulation's requirements. Also, if the proposed modifications are enacted, providers will have a one-year extension to revise their existing contracts with business associates.

2. CMS Releases Model Compliance Form to Obtain One-Year Extension to Comply with Electronic Transactions Regulation

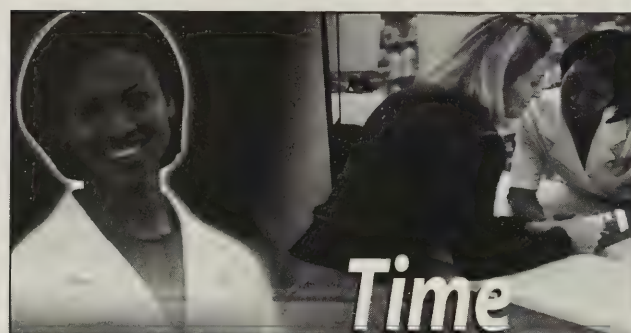
The Centers for Medicare and Medicaid Services (CMS) has released a model compliance plan that will allow providers to receive a one-year extension to comply with the new regulation governing electronic billing. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) required the Department of Health and Human Services (HHS) to adopt national standards for conducting health care

transactions electronically. The original compliance deadline for the electronic transactions rule was October 16, 2002, however, late last year Congress authorized a one-year extension to October 16, 2003. To receive the extension, a provider must file a compliance plan with HHS by October 15, 2002. The model plan and instructions on how to complete it are on the CMS website at <http://www.cms.hhs.gov/hipaa>.

Compliance plans may be submitted electronically on the HHS website at <http://www.cms.hhs.gov/hipaa> or mailed to:

Attention:
Model Compliance Plans
Centers for Medicare &
Medicaid Services
PO Box 8040
Baltimore, MD 21244-8040

HHS estimates that it will take approximately 15-20 minutes to complete and file a compliance plan. Providers and other covered entities that DO NOT submit compliance plans will not receive the extension and must comply with the original deadline of October 16, 2002.



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Interactions...

The Pharmacist Shortage: Emerging Careers Offer Competition to Traditional Pharmacy Practice

Today's pharmacy graduates have a much wider variety of careers to choose from than the graduates of a generation ago. When I graduated from pharmacy school, almost everyone went into community practice. A few, of course, opted for hospital and fewer still something else, such as industry. I stayed on for graduate school in pharmacy administration, preferring to study how pharmacists worked rather than work myself!

Today's pharmacy graduates, with a strong scientific background, deep clinical experience, and a moderate dose of management training are finding an ever-widening array of career choices available to them. As drug therapy has become both more complex, useful, and expensive, pharmacists are proving to be invaluable.

In primary patient care, pharmacists find opportunities to assess, manage, and monitor drug therapy. Many hospitals, from the Indian Health Service to the VA, from academic medical centers to community institutions, operate ambulatory clinics to manage complex therapies or to focus on specific diseases such as asthma or diabetes. Pharmacist-operated anticoagulant clinics have long since proved their worth. As the rapidly-filling pipeline of biotech therapies begins to release products to the marketplace, even more pharmacist positions will be created to take care of the special needs of patients on these unstable and difficult-to-manage products.

Prescription drug use is expanding and pharmacist workloads are increasing at the dispensing counter. It is pharmacists who are designing the systems of order fulfillment that use the latest in automation and computerized information technology. We will soon reach the point where computer imaging technology will make it unnecessary for pharmacists to do a final check on the physical product in a prescription. It is pharmacists who are designing these systems. It is pharmacists who will supervise and validate the quality of the technology.

Patient safety is a major issue in the nation's hospitals. With only the very sickest patients entering hospitals, the margin for error in drug therapy is diminishingly small. Pharmacists are finding new opportunities as medication safety officers, while others staff decentralized pharmacy units and attend rounds with physicians.

The number of pharmacists employed in non-patient care positions is also increasing rapidly. The pharmaceutical industry loves Pharm.D. graduates with residency training and a few years experience as teachers. These pharmacists make excellent medical education liaisons, much to the dismay of schools of pharmacy that themselves face major teacher shortages as enrollments expand.

The growth of the internet as a medium for communicating drug information has led to an increase in



David A. Knapp, Ph.D., Dean
University of Maryland School of Pharmacy

demand for pharmacists trained in drug information. Drug manufacturers, drug chains, PBMs, and insurance carriers are all starting webpages. They often have drug information components that must be managed. It is pharmacists who do the managing.

Pharmacists with additional training in a related field can find especially rewarding careers. Pharmacy law, pharmacy business, and pharmacy with information technology are examples of areas of rapid growth.

With imagination and initiative, pharmacy graduates can create jobs where there were none before. Recent Maryland alumnus Tina Bayuse, has become the first pharmacist in the American space program, having created her own position at NASA Headquarters in Houston.

The pharmacy workforce situation is not a simple one. It will not be solved by merely increasing

enrollment in schools of pharmacy. We not only have jobs going unfilled in the traditional fields of community and institutional pharmacy, but also are seeing the creation of new careers where none existed previously.

As a comprehensive school of pharmacy, the University of Maryland has an obligation to educate our students to be able to move into any of these fields or be able to seek the additional training needed to qualify. Our curriculum is diverse. It offers our students information about many careers and exposes them to lecturers and to rotations across the range of opportunities available. Over 20% of our curriculum is electives, permitting our professional students the widest range of choice of any school of pharmacy in the country. Upon graduation, our students are in the enviable position of having employers compete for them and that competition makes us all stronger.

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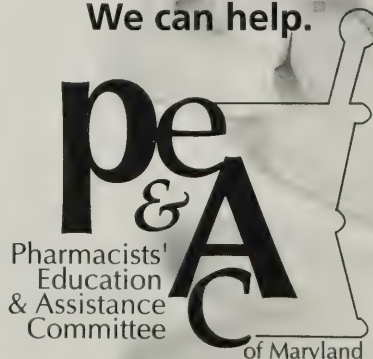


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AND THE LAW

By Don McGuire, R.Ph., J.D.

This series, **Pharmacy and the Law**, is presented by Pharmacists Mutual Insurance Company and your State Pharmacy Association through Pharmacy Marketing Group, Inc. a company dedicated to providing quality products and services to the pharmacy community.

"SWEAT THE DETAILS"

While self-help books may advise a person to not sweat the small stuff, this same advice is not necessarily good advice for the pharmacist.

Jerry Austermiller transferred his Coumadin prescription. The receiving pharmacist accidentally dated the prescription, written on March 11, 1996, with the date of the transfer, December 26, 1996. The prescription was filled twice after its true expiration date. Mr. Austermiller later died from the effects of the Coumadin.¹

Mrs. Johnson presented her prescription for Tavist D to the pharmacist at Sell Lower Pharmacy. Unfortunately, the state prescription program would not pay for Tavist D. The pharmacist was permitted by law to automatically substitute another product. The pharmacist wrote this new order on a telephoned prescription blank and threw the original written prescription away. The patient was later injured and when the claim was investigated, the physician denied ever ordering the Tavist D or the substitute.

Ron had dispensed phentermine made by ABC Pharmaceuticals for a

number of years. During one short period, Ron had to buy XYZ Drugs' brand of phentermine due to a supply problem. Ron figured it was only for a short time and it was a lot of work to update the computer when he was only going to change it back again in a few weeks. Mrs. Hitchcock's prescription was filled with the XYZ phentermine, but the computer profile indicated that it was filled with ABC's version. Later, ABC Pharmaceuticals was embroiled in a series of scandals and patients had alleged that ABC's phentermine was unsafe. Three years later, Ron was served with a lawsuit filed by Mrs. Hitchcock suing both him and ABC Pharmaceuticals.

The common theme to all of these scenarios is record keeping. Record keeping is not the most glamorous function performed in the pharmacy, but it is vital. Documentation of the pharmacist's professional activities is absolutely necessary. Luckily, the vast majority of records created are never reviewed again. However, this creates a feeling of "I'm wasting my time" and tempts the pharmacist to skip over the details.

Let us examine our examples as if the record keeping had been accurately completed. In Austermiller, the final two refills would not have been filled had the

¹.) *Austermiller v. Dosick, et al.*, 2001 WL 1664104 (Ohio App. 6 Dist.) December 31, 2001

correct expiration date been placed on the prescription. The pharmacy would not have been embroiled in the lawsuit (they ultimately settled) and Mr. Austermiller may be alive today.

If the pharmacist had drawn a line through the Tavist D and written his change, "per state formulary", on the prescription blank, the pharmacist would have ready proof that the physician did in fact prescribe the Tavist D. This would have been invaluable in resolving the patient's claim.

Proper documentation of the manufacturer's product being dispensed would have helped Ron obtain a dismissal in the case when he had not dispensed ABC's phentermine to this patient. However, this highlights the two-edged sword of documentation. Had Ron kept accurate records of which phentermine brand was dispensed, those records would clearly indicate the instances in which ABC's product was dispensed. Pharmacy practice has enough risk without exposing ourselves to unwarranted and undeserved lawsuits. Accurate record keeping will limit exposure to those risks that may be warranted.

In addition to these liability concerns, pharmacists are generally charged by their state boards of pharmacy with the duty to keep accurate records. Failure to do so may expose the pharmacist to sanction by the state board. Also, audits of prescription files by third party carriers that uncover inaccurate records could result in a demand for repayment. Many times these have been substantial demands.

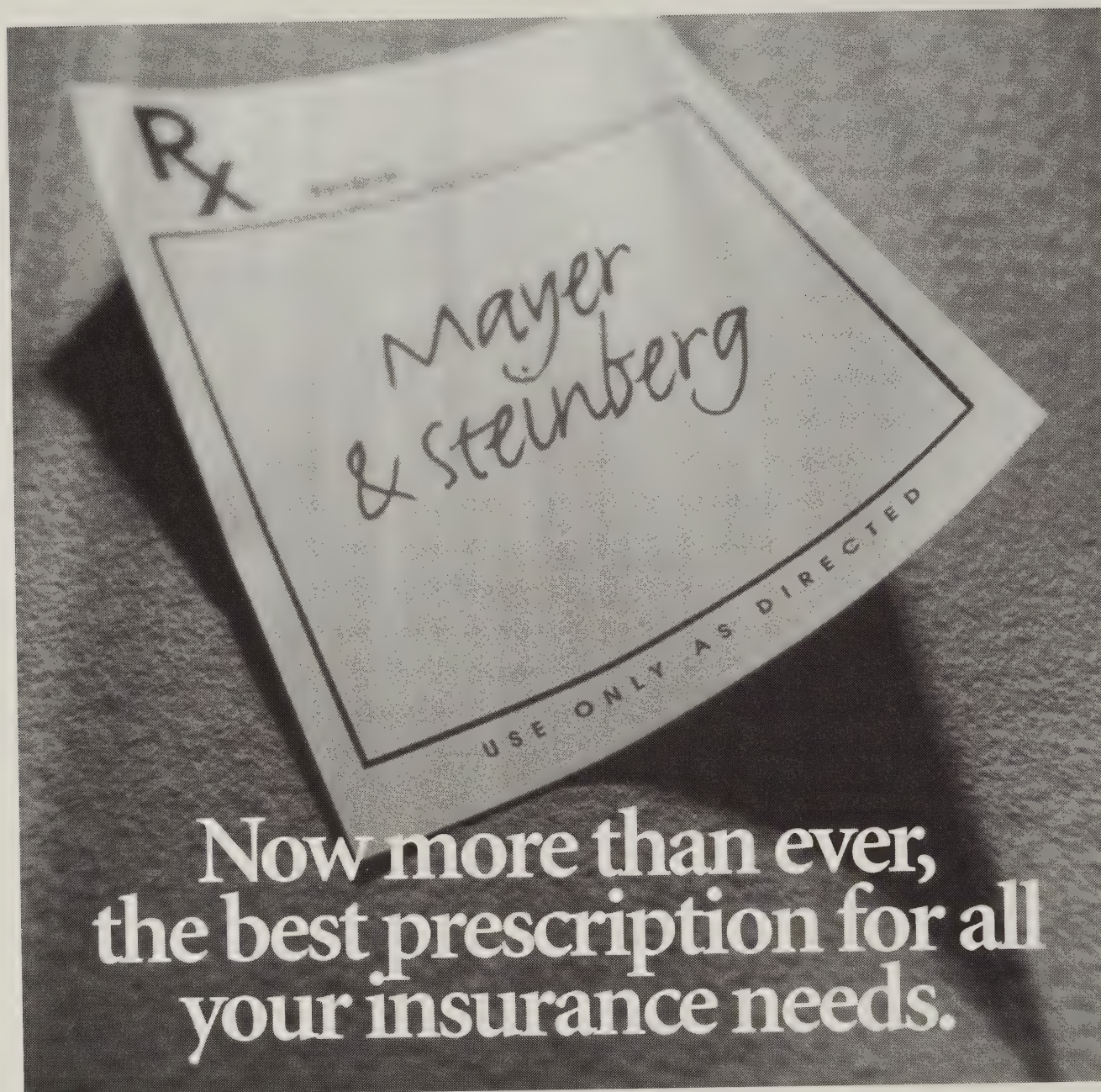
Record keeping is an important, if not always exciting, part of pharmacy practice. Proper records can limit liability exposure, protect the pharmacist's professional standing, and limit exposure in third part audits. It is also the right thing to do. Sweat the details.

© Don McGuire, R.Ph., J.D., is a Professional Liability Claims Attorney at Pharmacists Mutual Insurance Company.

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with the policies and procedures of their employers and insurance companies, and act accordingly.

2002 General Assembly Report

Bill Number	Content	Result
SB 22	Osteoporosis Prevention and Education Task Force (Pharmacist Added)	Passed
SB 44	Required Electronic Submission of all CDS Prescriptions to DHMH	Failed
SB 234	Catastrophic Health Emergencies (Powers of the Governor and the Secretary of Health and Mental Hygiene)	Passed
SB 235	Governor's Emergency Powers	Passed
HB 329	Health Care Whistleblower Protection Act (Amendment, must report to employer before Board of Pharmacy)	Passed
SB 418	State Board of Pharmacy - Sunset Extension (Extends Board of Pharmacy to 2013 - limits discovery by establishing permit holder designee as medical peer review committee)	Passed
SB 269	State Advisory Council on Pain Management (Pharmacist Included)	Passed
SB 45	Forgery of CDS Prescriptions - Makes a felony of all forgeries	Failed House
SB 676-HB 781	Drug Therapy Management - Collaborative Practice allows pharmacist and physician to enter into therapy management contract	Passed
HB 761	Pharmacy Benefit Management Regulation Act (NCPA bill)	Failed
HB 1141	State Advisory Council on Quality Care of End of Life (pharmacist added)	Passed
SB 623	DHMH proposed budget for Medicaid prescription drugs - Supplemental rebates, prior authorization, preferred drug list, pharmacy and therapeutics requirements and utilization review, dispensing fee study, October 1 deadline to identify if savings measures achieved goal without reduction of AWP from -10% to -13%	Failed House (would not agree to supplemental rebates)
SB 481	Amended to Include all Pharmacy Medicaid Favorable Language with the Exception of Supplemental Rebates from Manufacturers	Passed



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Latest Research Unleashes Sleeping Genie 50 Years in the Bottle

By John Parks Trowbridge, M.D., FACAM

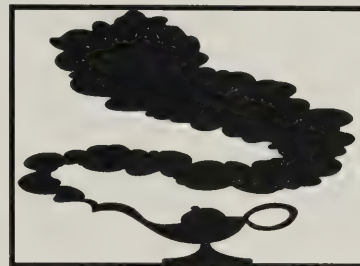
Chelation—incorporation of a metal ion into a heterocyclic ring structure; this binding process provides the bio-inorganic chemical basis for therapeutic applications.

You're in 1952, postwar America is building cars as fast as the exuberant economy can buy them. You're a Detroit internist with a specialty interest in heart disease, which surprisingly has just become recognized as our number one killer. And you're a "company doctor" for workers in one of the auto battery factories.

With the hectic pace of expanding production, numbers of workers complain of vague illness symptoms. You check them out—and find lead poisoning from their work with battery plates. You recall reading a brief paper in the Medical Annals of District of Columbia a few weeks earlier—the first report of successfully removing lead from a child acutely poisoned from chewing on a window sill with lead-based paint.

Vague complaints and fatigue disappear within weeks with this new treatment. The workers who also have heart disease are commenting that they are having fewer angina chest pains, are needing less nitroglycerin, and are no longer short of breath. Curious, you try this new "lead" treatment on some of your "heart" patients who don't work in the battery factory. They, too, show dramatic improvements with heart disease symptoms.

Voila! You've just witnessed the unexpected discovery of chelation therapy as an effective treatment for heart and blood vessel diseases by Norman E. Clarke, Sr., M.D.² He went on to publish several reports of stunning successes. Good science is often just good luck. The unlucky part is that chelation (pronounced key-LAY-shun) with EDTA (ethylene diamine tetraacetic acid) fell to the side as newer cardiac drugs were developed and as bypass surgery appeared in 1966. (Figure 1)



Chelation therapy is a prescribed medical treatment, offered only by licensed, trained *physicians*—just the same as operations are offered only by licensed, trained *surgeons*. Chelation is used to "turn on" body repair and healing processes. This can lead to better function of body cells and organs—and improved blood flow to many areas of the body. The results can be remarkable for many patients.

Chelation appears to be very useful and needed even after heart or blood vessel surgery. Clinical experience suggests it can help slow or perhaps prevent the recurrent blocking that is common for arteries that have been "bypassed" or "ballooned." Even more, chelation can help improve circulation through the tens of thousands of miles of *other* blood vessels, restoring improved health.

Chelation may be helpful for a broad range of medical conditions, especially where patients need *continuing* medications, or need an *increasing number* of medications, or *continue to worsen* slowly despite being on medications, or are needing drugs with *increasingly dangerous* side effects.

Chelation Removes Metals, Pure and Simple

Swiss Chemist Alfred Werner first described the chelation process in 1893, fascinated by these ring "meta-ligand complexes" that were later found essential in biology. His discovery won the 1913 Nobel Prize because of its fundamental explanation of nature. The "red" in blood is iron chelated by hemoglobin; the "green" in plants is magnesium chelated by chlorophyll. This metal-binding property stimulated research in Great Britain between the World Wars, in hopes of finding an antidote if nerve-gases (arsenic compounds) were used again. The Germans had

another agenda: knowing citric acid imports would cease in a coming war, they sought chelators to remove calcium from "hard water" that interfered with dye processes for fabrics. EDTA was the most useful chemical warranting further investigation.

EDTA, the major chelator in clinical use at present, has shown its effectiveness at removing several toxic metals from the body, in the following order: (highest) ferric iron, mercury copper, lead, nickel, cadmium, and ferrous iron (lowest).⁴ An additional desirable effect of EDTA is to trigger the redistribution of calcium from abnormal sites (in mitochondria, in tissues, in arterial plaque) to its normal zones (teeth and bones, so chelation can help improve osteoporosis).³

"Transition" metals such as copper and iron can promote oxidation reactions and have been implicated in the lipoprotein oxidation which may contribute to CVD.⁴ The mechanism appears similar to that for toxic "heavy" metals. Further, disease changes in acid-base chemistry often can be monitored by abnormal iron transport, specifically as elevated ferritin level, which appears to increase with metabolic acidosis. Restoration of normal iron transport—via transferrin instead of by ferritin—appears to be correlated with more normal cellular alkalosis, reflected in improved general health.

Chelation appears to stimulate natural healing processes by removing excess iron and toxic metals lodged in body organs, by changing calcium balance, and by reducing "rusting" damage (so-called "free radical" injury⁵). One of the first improvements is in mitochondrial efficiency; providing more energy to run the metabolic processes within cells.⁶ The body responds to these changes by removing the calcium that is hardening tissues and blocking arteries, by allowing more blood flow to organs, by improving overall function, and by creating in the patient a feeling of being more "at ease" instead of "dis-eased."

Easy, Safe, Comfortable Treatments

Taking the mystery out of this treatment process explains how easy and painless it is. If a patient qualifies for chelation treatments after an appropriate evaluation, the next step is an "informed consent" conference with the trained physician, to answer all questions. Treatments are done in a relaxed setting, in a special room in the doctor's office - sometimes in comfortable reclining chairs. An office nurse places a tiny 25G needle into a vein in the hand or arm, and a freshly-prepared solution formulated for that particular patient (based on kidney function, weight, stage, and goals of treatment, and so on) drips gently in from an IV bag. During the one to three hours or so that it takes

to receive a treatment, patients talk, exchange their success stories, read, or watch TV.

Treatments are given weekly for a period of about six to 12 or more months, depending upon individual needs. Periodic blood and urine tests monitor progress, especially removal of toxic heavy metals. After the desired benefit level is reached, the patient is usually advised to continue a maintenance program of once-monthly treatments to help preserve (and often improve) personal well-being.

Rejuvenate the Arteries to All Organs

Changes caused by the chelation treatments can help improve cell health and blood circulation to—and inside—all organs of the body. And that is one mechanism that explains why chelation appears remarkably helpful in so many different disease conditions.

Chelation therapy makes the walls of blood vessels softer and more flexible, by helping the body remove abnormal calcium deposits associated with disease and aging. Chelation can help more blood to flow to all organs. Bypass operations "jump over" or remove blockages in only a few dozen inches or feet of bigger blood vessels. But chelation helps to improve the condition of thousands of miles of bigger and smaller blood vessels—the very ones upon which all organs depend in order to function. Improving blood flow to organs which are "in trouble" almost always improve their function.

Why Treat Inches When Chelation Treats Miles?

While coronary bypass surgery is variously reported to cost between 25 to 45 thousand dollars, patient reports often describe costs up to 75 or more thousand dollars. And CAGB still deals only with a few inches or feet of the many thousands of miles of blood vessels in the body. And bypass surgery does absolutely nothing to stop more and more hardening and blockage that is occurring in many arteries. Even other operations endarterectomy (clean-out) surgery (for carotid neck arteries and others) and graft insertion surgery (for abdominal, leg arteries, and others)—still deal only with a few inches or feet. Artery degeneration and blockage changes are caused by biochemical imbalances ongoing throughout the body. Further, neurological "changes" can occur in almost 80 percent of bypass patients, despite the many advances made in cardiac surgery.

In contrast, "iv" chelation therapy can cost from 5 to 15 thousand dollars and directly improves chemical and calcium imbalances. It removes toxic metals that

injure blood vessels linings and helps restore cell energy systems that are critical for healing and repair. Chelation does this for all the arteries, capillaries, and veins throughout the body, including areas where surgery simply isn't possible—such as inside the liver, kidneys, pancreas, brain, and other vital organs. Patients uniformly feel better, often all over. Surprisingly, chelation is not considered by most physicians as a real alternative to drugs and popular surgical procedures.

Chelation's Exceptional Safety Record

Dr. L. E. Meltzer's group reviewed the side effects in patients treated with acceptable chelation dosages in 1961, publishing in the *American Journal of Medical Science*.⁷ Their conclusion, after 2,000 treatments given to 81 patients, was that "... the drug can be used without danger over prolonged periods." The FDA restated its same conclusion from decades earlier when approving in 1988 a clinical research proposal to study chelation in peripheral arterial disease. Doctors Olszewer, Sabbag, and Carter reaffirmed this remarkable safety record in their 1996 article that summarized experience with more than 2 million iv-infusions in more than 100,000 patients in the prior 11 years: just like many other drugs, chelation therapy is safe when given in acceptable dosages, as described in the protocol designed by chelation experts.⁸

Is Chelation the "Mainstream Medicine" of Tomorrow?

For 50 years, "mainstream" medicine has claimed that chelation is "quackery" because its practitioners described improvements with so many different disease problems. Now better analytical chemistry has demonstrated that virtually everyone has become overloaded with toxic heavy metal—which damage most human functions and for which chelation is the only known treatment. The time for doctors to "play ostrich" and ignore mounting scientific evidence has long passed. Patients, frustrated with spending more money, taking more drugs, and feeling steadily worse, are demanding safe and effective treatments for "whatever ails them." Chelation may offer one of the greatest tools ever discovered to rejuvenate human health. The Genie may truly be "out of the bottle."

Chelation History Landmarks

1893	Swiss chemist Alfred Werner describes chelation ("complexion"/complexes) chemistry, awarded Nobel prize in 1913
mid-1930's	Munz in (Nazi) Germany first synthesizes EDTA
1941	Berwerth files first U.S. patent for EDTA
1945	English scientists develop BAL, "British Anti-Lewisite," (Lewisite=arsenic nerve-gas), beginning the era of chelation therapy as a pharmaceutical treatment (first "designer-drug?")
1951	Rubin explores calcium chelating properties of EDTA, develops "lavender-top tubes" for laboratory blood collection
1952	Rubin and clinical colleagues use Ca-EDTA on child with lead encephalopathy, creating massive urinary lead excretion and significant clinical improvement
1952	Norman E. Clarke, Sr., the "Father of Chelation Therapy in America," observes improvement in patients with cardiovascular disease
1955	Harman describes free radicals as mechanism in aging and disease
1959, 1960	NIH research physician Seven holds "Metal-Binding in Medicine" symposia
1961	Seven dies, dramatically slowing chelation research
1969	EDTA patent expires, leaving "orphan drug" before much clinical research underway
1970's	Advances in cardiovascular surgery capture public attention and research funds
2001	Nanobacter treatment results catapult chelation back into spotlight

(Figure 1)

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John Parks Trowbridge, M.D., FACAM, serves as the Chief Medical Consultant to Life Celebrating Health Association in Humble, Texas. He was certified as a specialist by the American Board of Chelation Therapy in 1985. Among his many accomplishments in his career he has written three best-sellers and is currently in preparation for his latest book "Healing your Headaches."

Texas Pharmacy, Spring 2002

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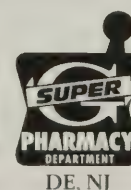
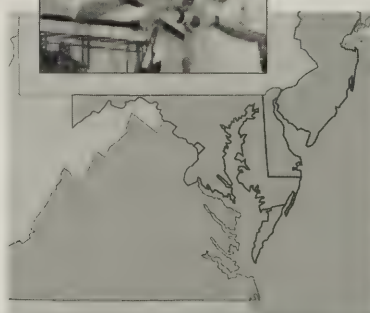
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120th Anniversary

Maryland Pharmacists Association
120th Annual Convention
Saturday, June 8 - Tuesday, June 11, 2002
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Join Us

We hope you will enjoy the many educational, professional and social events planned for this year's convention. Come to Oceanfront luxury and enjoy the fun and excitement that comes with being at the beach.

Continuing Education

The continuing education programs offered at this year's convention are the latest in both traditional and non-traditional therapies. Learn about the hottest topics in pharmacy and earn approximately 20 contact hours of continuing education.

Trade Show & Job Fair

Connect to your future. Visit the exhibits on Monday, June 10. *During lunch*, you will find displays of the latest innovative products and services. You may also find if the grass is greener on the other side. Meet with prospective employers in a casual, nonintimidating setting (with no business suits or appointments). **No one under 16 years of age will be allowed on the exhibit floor.**

Social Events

Enjoy the laid-back atmosphere of the beach and come to the President's BBQ Cookout, Crab Feast, and Award Reception and Banquet. Enjoy the best that Maryland has to offer—all in Ocean City. Have fun and relax with friends and family. There will be lots of great food!



What to Wear

Casual attire is appropriate for all education sessions and for the evening social activities. *The Awards Reception and Banquet is business attire.*



Raffle

Take a chance! Raffle tickets will be sold for a chance to win a 10-day Caribbean cruise for two out of Baltimore, a HP Personal PC, or Weekend for Two at the Homestead in Virginia. Tickets are \$ 5 each or 5 for \$ 20. You do not need to be present to win. Proceeds will benefit the MPhA Foundation.

Advance Registration

Please complete the registration form included in this brochure. Type or print clearly and return the form with your check or credit card information to: **MPhA Annual Convention 650 W. Lombard Street, Baltimore, MD 21201-1572**. If you are paying with a credit card, you may FAX your registration to MPhA at 410-727-2253. Register before the deadline and save the \$40 on-site fee. **The deadline for Advance Registration is Friday, May 24, 2002.**

On-site Registration

Registration forms received after the advance registration deadline will not be processed. You will need to register when you arrive at the Sheraton and add the \$40 on-site fee.

Registration Fees



Review the registration categories below to determine what is included in your fee.

- **Full pharmacist registration** fee includes all breakfasts, admission to all CE sessions, beverage breaks, lunches and all evening events.
- **Full spouse/guest registration** fee includes all breakfasts and all evening events. *(Fee does not include lunches or the Trade Show & Job Fair.)*
- **Child registration** fee includes all breakfasts and the President's BBQ Cookout on Saturday evening. *(Fee does not include lunches, the Trade Show & Job Fair, Crab Feast or Awards Reception/Banquet.)*
- **Student registration** fee includes all breakfasts, admission to all CE sessions, beverage breaks and lunches. *(Fee does not include the President's BBQ Cookout, the Crab Feast or Awards Reception/Banquet.)*
- **Daily registration** fee includes breakfast, admission to all CE sessions, beverage breaks, and lunch if served for that day. *(Fee does not include the President's BBQ Cookout, the Crab Feast or Awards Reception/Banquet.)*

If you have any questions about the program and/or registration, please contact the Maryland Pharmacists Association at 410-727-0746, or toll-free in Maryland 1-800-833-7587.

Registration	Breakfast	CE Sessions	Beverage Breaks	Lunch	President's BBQ Cookout	Crab Feast	Reception & Banquet
Pharmacist	X	X	X	X	X	X	X
Spouse/Guest	X				X	X	X
Child	X				X		
Student	X	X	X	X			
Daily	X	X	X	X			

Registration Cancellation

To cancel your registration and receive a refund, a written request must be received by Friday, May 24, 2002. Cancellation requests received by this date will be processed and a refund issued less a \$25 processing fee. Please allow 4-6 weeks for processing. All requests received after Friday, May 24, 2002, will mandate a 100% forfeiture of monies paid.

Hotel Accommodations



The Clarion Resort Fontainebleau is offering discounted hotel rates for MPhA attendees. To reserve your room, call the Clarion directly at 1-800-638-2100. You must tell the reservation agent you are with the Maryland Pharmacists Association to receive the special rate. A deposit equal to one night's stay is required to hold the reservation. Currently an 9% state and local tax is applicable to the room rates. **The deadline is Wednesday, May 8, 2002.**

Hotel Cancellation

Reservation cancellations must be made 72 hours prior to scheduled arrival to avoid a full room rate "No Show" charge. If you cancel, you must have a cancellation number to receive a refund. If you plan to shorten your length of stay, you must notify the hotel at or before check-in to avoid an early check-out fee of \$149.

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Double/Double	\$149	<u>Condos</u>	
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Cabana	\$289	3 Bedroom	\$319

Special Needs

If you require special accommodations or meals to participate in this educational program, please provide written information about your requirements to the Maryland Pharmacists Association at least ten (10) business days in advance of the meeting.

Schedule at a Glance

(ACPE Accreditation will be obtained for each program)

Saturday, June 8

- 12:00 - 5:00** Registration
- 1:00 - 1:55** "Management of Chronic Kidney Disease and Renal Transplant"
Presenter: Tess Behrens, MD
Sponsor: National Kidney Foundation, MD Chapter
- 2:00 - 2:55** "Lowering Cholesterol in the Community"
Presenter: Renee Hilliard, Pharm.D.
Sponsor: Pfizer
- 3:00 - 3:15** Beverage Break
- 3:15 - 5:15** "HIPAA Administrative Simplification"
Presenter: David Sharp, Ph.D.
Sponsor: MHCC
- 6:30 - 9:00** **President's BBQ Cookout**
Sponsored in part: EPIC

Sunday, June 9

- 7:00 - 5:00** Registration
- 7:00 - 9:00** Breakfast
- 8:15 - 9:45** "Home Blood Pressure Monitoring: A Hands on Workshop"
Presenter: Rick Reilly, MBA
Sponsor: McKesson & Omron Health
- 9:45 - 10:00** Beverage Break
- 10:00 - 12:00** "Biological & Chemical Terrorism—Health Care Implication"
Presenter: William Mencia, M.D.
Sponsor: Merck
- 12:00 - 1:25** Lunch - House of Delegates
Sponsor: Purdue Pharma
- 1:30 - 2:30** "Management of Non-Malignant Pain"
Speaker: Mathew Gainey, Pharm.D.
Sponsor: Purdue Pharma
- 2:30 - 4:30** "Drug Therapy Management—New Maryland Law"
Presenter: Magaly Rodriguez de Bittner, Pharm.D., BCPS, CDE
- 3:30 - 3:45** Beverage Break
- 6:30 - 9:00** **Crab Feast**

Monday, June 10

- 7:00 - 5:00** Registration
- 7:00 - 9:00** Breakfast
- 7:00 - 9:00** Trustee Breakfast - Meeting
Sponsor: Pharmacia
- 8:00 - 9:55** "From Anecdote to Evidence: Science-based Herbal Remedies that help Cope with Hepatitis"
Presenter: Phillip A. Duturme, Ph.D.
Sponsor: Himalaya USA
- 10:00 - 11:55** "Introduction to Homeopathic Medicines for Pharmacists"
Presenter: Ronald Boyer, M.D.
Sponsor: Boiron
- 10:45 - 11:00** Beverage Break
- 12:00 - 2:00** Lunch - **Trade Show & Job Fair**
- 2:00 - 2:55** "Advances in the Management of Hepatitis C"
Presenter: Roberta Strohl, RN
Sponsor: Schering
- 3:00 - 3:15** Beverage Break
- 3:15 - 5:00** House of Delegates
- 7:00 - 10:30** **Awards Reception & Banquet**
Sponsor: McKesson

Tuesday, June 11

- 7:00 - 12:30** Registration
- 7:00 - 9:00** Breakfast
- 8:00 - 8:55** "GERD"
Presenter: Barry Kaufman, M.D.
Sponsor: TAP Pharmaceuticals
- 9:00 - 9:55** "NSAID Related GI Disorders and Colorectal Cancer"
Presenter: James Novick, M.D.
Sponsor: TAP Pharmaceuticals
- 10:00 - 10:15** Beverage Break
- 10:15 - 12:15** "Blood Glucose Monitoring"
Presenters: Joe Rizzo
Sponsor: McKesson & Roche Diagnostics

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☐ Full time Pharmacy Student	(\$35)	_____

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☐ Non-Member	_____ @ (\$110)	\$ _____

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Crab Feast

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Awards Reception and Banquet

☐ Adults/Pharmacy Students	_____ @ (\$45)	\$ _____
☐ Child Under 12	_____ @ (\$20)	_____

House of Delegates ☐ Lunch (Sunday) _____ @ (\$15) \$ _____

Trade Show & Job Fair ☐ Lunch (Monday) _____ @ (\$15) \$ _____

Total Fee \$ _____

So that we may better plan, please indicate the events you expect to attend:

	Yes	No	Number
Saturday, June 8			
President's Cookout	☐	☐	_____

Sunday, June 9			
Breakfast	☐	☐	_____
Lunch	☐	☐	_____
Crab Feast	☐	☐	_____

Monday, June 10			
Breakfast	☐	☐	_____
Lunch	☐	☐	_____

Awards Banquet **	☐	☐	_____
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** Circle One Chicken or Salmon

Tuesday, June 11			
Breakfast	☐	☐	_____

ADA Compliance:

Please attach a written description of the dietary or special assistance needed. MPhA cannot assure the availability of appropriate accommodations without being notified ten (10) business days in advance of the meeting.

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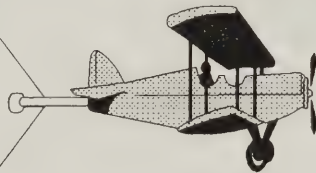
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KAVA

Safety is Questioned...

Link to possible liver toxicity subject of inquiries

by Mark Blumenthal

The biggest subject on the front burner in the herb community in the past six months is the potential hepatotoxicity of kava. European regulatory officials have begun investigating kava based on case reports of liver toxicity associated with the popular South Pacific herb. News stories first began surfacing in November 2001, increasing in December 2001, culminating at the end of the year with a front-page article in *USA Today* (Rubin, 2001); in mid-January after *The New York Times* (Burros, 2002) and *Washington Post* (Packer-Tursman, 2002) published articles, things started picking up again, culminating in an *Associated Press* article that was carried in presumably hundreds of papers across the country (Neergard, 2002).

The American Botanical Council (ABC), has been very interested in the issue surrounding the case reports of hepatotoxicity associated with ingestion of kava since isolated reports became known in 1999 (Strahl, 1998). Subsequently, news of possible European regulatory action began to surface as increased reports became available last fall. ABC has been collecting an extensive volume of data on this subject and has been in contact with German regulatory officials, lead scientists at universities and phytomedicine manufacturers here and in Europe and industry trade organizations in Germany and the United States.

What follows is an attempt to put some of the kava situation into a chronological perspective. This article will not, however, attempt to evaluate the safety issue itself, since that task is being addressed by more qualified experts.

Kava is the traditional ritual tranquilizing beverage from the rootstock of *Piper methysticum* G. Forster, a plant in the family Piperaceae (pepper family). It has long enjoyed a reputation as the most revered medicinal and ritual herb in Polynesia, where it is used for ceremonial purposes, as a symbolic welcome for VIPs, as a beverage for culminating the marriage ceremony, as a medicine for relaxation, and to treat urinary tract infections (Singh and Blumenthal, 1997). There have been at least 13 clinical studies conducted on 619 participants demonstrating Kava's positive effects for indications including anxiety; mental function, reaction time, sleep quality; and perimenopausal symptoms (Blumenthal et al., 2002), with a meta-analysis demonstrating that kava is more effective than placebo in treating symptoms of anxiety (Pittler and Ernst, 2000). Because of its historical use and modern scientific data to demonstrate safety and efficacy; the German Commission E, a special expert committee of the German Federal Institute for Drugs and Medical Devices (BfArM), analogous to the U.S. Food and Drug

Administration (FDA), has approved kava preparations as nonprescription drugs for the treatment of anxiety disorders, stress, and restlessness (Blumenthal et al, 1998).

Kava in Europe

At least 28 cases of liver toxicity associated with the use of kava have been reported in Switzerland (4) and Germany (24), prompting regulatory actions by authorities (Hagemann, 2001). The hepatic adverse event reports (AERs) in these cases include cholestatic hepatitis (inflamed liver with obstruction of bile flow), icterus (jaundice), increased liver enzymes (a sign of liver dysfunction), liver cell impairment, severe hepatitis with confluent necrosis, irreversible liver damage (required transplant in four cases), etc. Several additional cases have been reported in Switzerland.

Based on the initial four case reports in 2000, Swiss officials banned a trademarked, acetone-based kava extract called Laitan®. This was a highly concentrated product, standardized to 70 percent kavalactone content (also sometimes referred to as kavapyrones, manufactured by a leading German phytomedicine company, W Schwabe (Karlsruhe, Germany). While only the acetonetic extracts were removed from the Swiss market at this time, the government gave manufacturers of ethanolic extracts three years to market these products and monitor

their safety to see if any liver problems were reported. In addition, all manufacturers of ethanolic extracts in Switzerland have been asked to substantiate safety by conducting new toxicological and clinical trials (this may pose a significant financial challenge to these mostly small companies).

It should come as no surprise that the initial reports in Switzerland pertain to the acetone extract; since it dominates the market there with an approximately 80-85 percent share. Ethanolic extracts comprise the balance. Ironically, the acetone extract has been the subject of the most scientific scrutiny; with at least seven controlled clinical trials on this product indicating its safety and efficacy compared to placebo (Pittler and Ernst, 1999; Blumenthal et al, 2002). Interestingly, the decision by the Swiss authorities was made despite the lack that in three cases other potentially hepatotoxic drugs had been taken (e.g. diclofenac), and concurrent viral infections and alcohol use or abuse could not be ruled out.

In 2000, the BfArM, called for the labeling of such potential risk on package inserts into Kava products (BfArM, 2000), in response to the potential for hepatotoxicity. Then, on November 8, 2001, officials at the BfArM sent letters to kava manufacturers proposing withdrawal of drug licenses for kava (Hagemann, 2001). Although kava is approved as a safe and effective nonprescription drug by the German Commission E, much of the kava sold in Germany also is prescribed, as many physicians consider it a safe and effective first-line remedy to treat symptoms associated with anxiety, a condition for which it is approved. The action proposed in the

November 8 letter from BfArM is pending evaluation of data submitted by the companies. These submissions originally were to be made within four weeks; however, an extension was granted until December 21, 2001. During this time, the pharmaceutical giant Merck permanently ceased sales of its kava products Kavadura® and KyttaKava®, according to a story attributed to the *Financial Times* (Anon, 2001).

On December 18, 2001, the German Nonprescription Drug Manufacturers Association (BAH) and the German Pharmaceutical Industry Association (BPI) filed comments with BfArM (BAH-BPI, 2001) as did several individual parties (Schmidt, 2002; Schulz and Siegers, 2001). The BAH-BPI comments noted "... in most of the reported cases, the causality between kava intake and liver reactions is not clear because further medication was used which might have caused liver toxicity. Furthermore, in many cases, detailed information on the patients' history, co-medication, consumption of alcohol, and further particulars are missing, thus not permitting a sound evaluation of these cases." Some of these comments proposed that kava remain on the market as a prescription drug to be used under the supervision of a physician, where the patient's medical history, and potential susceptibility to liver disease and liver enzyme levels could be monitored to help reduce the potential risk of hepatotoxicity. Discussing the already-existing disclosure of potential hepatic risk in kava package inserts, as required by BfArM in 2000, Barbara Steinhoff, Ph.D., of the BAH, stated that the BAH submission "comes to the conclusion that the data presented [i.e. to the BfArM] on the benefit/risk assessment of Kava-

and Kavain containing medicinal products does not justify the withdrawal of marketing authorizations. The companies have already included risk information in their package leaflets and expert information and consider control of patients applying Kava products by a physician as an appropriate means." (Steinhoff, 2001).

Some comments submitted to BfArM evaluated the details of the AERs, showing that many were related to the concomitant use of conventional drugs with potential hepatotoxic effects, and other issues that raised doubts about the validity of some of the reports (Schmidt, 2001). It is not certain when the BfArM will complete its review of the industry's comments. The fate of kava on the German market has been slightly clarified at the time of this writing (mid February 2002). In late January 2002, a special committee of the BfArM that evaluates drugs for prescription use recommended that BfArM approve kava as a prescription drug (Busse, 2002). This approval was consistent with some of the comments from German manufacturers who would rather see kava be retained on the market than to see it be banned from use. It is likely that kava will be approved as prescription starting in July 2002.

Meanwhile, the German situation has set off a chain reaction of scrutiny by other governments and a spate of articles in Europe, the United States, and elsewhere. In early December, members of four major U.S. dietary supplement trade associations—the American Herbal Products Association (AHPA); the Council for Responsible Nutrition (CRN); the National Nutritional Foods Association (NNFA), and the Utah Natural Products Alliance

(UNPA)—initiated a meeting with Christine Lewis Taylor of the Center for Food Safety and Applied Nutrition of the FDA and other FDA officials to apprise them of the situation in Europe and the actions being taken by the U.S. industry, i.e., retaining a professional toxicologist to review to European AERs. On December 18, in a second meeting with the industry groups, the FDA announced that it was sending a letter to physicians requesting that they submit reports of cases of liver toxicity associated with the herb to the FDAs MedWatch system (Taylor, 2002). The FDA letter was not intended as a public warning but was merely a fact-finding measure. The letter was posted on the FDA website (www.fda.gov) and began to generate inquiries from the media during the following days.

On December 19, 2001, the dietary supplement industry in the United Kingdom, working with officials at the Medicine Controls Agency, agreed to voluntarily suspend Kava sales until such time as the question of liver toxicity is resolved (Woodfield, 2001). Boots, a leading drug chain in the UK, had previously suspended sales. According to reports from the UK, there are no published cases of liver toxicity associated with kava.

In January 2002, the French government banned kava products. The Belgian government reportedly has required kava warnings to be posted in drugstores, and the Dutch government has reportedly worked out an arrangement with the industry to require more detailed label warnings on kava products. In February 2002, the Irish government has reportedly banned the sale of Kava products.

A review of the cases reported in Germany and Switzerland,

based on the information available so far, is instructive. Of the 30 cases reported, 18 appear to be associated with the concomitant use of prescription medications, some of which are known or suspected to be hepatotoxic. In some instances, people consumed kava at higher than the doses recommended by the Commission E (60-120 mg kavalactones per day); one report shows that the subject exceeded this dose by 400 percent. Experts point to other

So the question is how can one resolve the apparent discrepancy in the FDA's reports on kava, from the 35 on the FDA's website in November (including the "fx" reports), to the 25 obtained by AHPA in January, to the 60 reported by The New York Times in January 2002? The answer lies in the fact that the reports on the FDA website had not been updated since October 1998; that is, they are more than three years old with no additional revisions!

potentially confounding co-factors that raise questions about kava's culpability. Whether some of these AERs are results of the conventional drugs, the interaction of kava and the conventional drugs, or the kava products used still remains to be determined. Adequate information is lacking for a proper assessment at the time of this writing although a review of the AERs by a pharmacologist for AHPA is imminent (mid-February).

Several analyses have turned a critical eye on these reports (Schmidt, 2002; Schulze and Siegers, 2002). The most

impressive, from Professors Johanne Schulze and Claus-Peter Siegers of the Medical University of Luebeck in Germany, concludes that although the association of kava and hepatotoxicity was reported as early as 1990, this issue did not attract much scientific or medical attention until 1999. Despite the fact that numerous spontaneous adverse event reports suggest the potential of kava hepatotoxicity, a definite causal relationship has been confirmed in one case only. The increase in the number of spontaneous reports may be due—in addition to possible intrinsic kava hepatotoxicity—to increased awareness of medical and regulatory officials, chronological association and aggravated pre-existing liver disease. They also point out that duplicate reports and erroneous association of kava in cases of preexisting liver damage has occurred. The most suitable therapeutic alternatives are the class of conventional drugs known as benzodiazepines (e.g., Valium) and antidepressants, which in some cases are known to exert drug toxicity including hepatotoxicity. These researchers acknowledge that kava preparations can produce adverse reactions (as noted by the Commission E monograph), and may be associated with rare serious liver toxicity. Schulz and Siegers suggest that the current data support idiosyncratic reactions as the possible mechanism rather than dose-dependent direct toxicity. They conclude that despite the wave of AERs, kava still appears to be a reasonable alternative for long-term treatment of anxiety; although suitable precautions should be taken to minimize patient risks.

AERs in the USA

Regarding kava in North America, the information is somewhat

confusing. In November 2001, both the ABC and AHPA checked the FDA database of AERs related to herbals and dietary supplements and found no reports of adverse liver effects associated with kava in the United States. There were, however, 35 AERs suggesting other types of adverse effects *purportedly* associated with kava use (as of November 26, 2001). A closer inspection of those AERs reveals that 29 of them are based on the infamous "fX" case in which a young man doled out ersatz "kava" doses at a New Year's Eve rave in Los Angeles in 1996. The fraudulent products contained 1,4-butanediol and contained no kava or any other herbs or natural dietary supplement ingredients (Anon., 1997). This case received widespread publicity the perpetrator's parents' business (where he stealthily manufactured the illicit product) was closed by health authorities, and he served a prison sentence. Thus, these AERs have nothing to do with kava and should not even be reported as kava AERs in the FDA database. AHPA has contacted the FDA and asked the agency to remove these erroneous and highly misleading reports (McGuffin, 2002b). FDAs Dr. Christine Taylor advised AHPA that the FDA press office has been directed to inform the press that these are not kava-related cases.

The New York Times' article on January 16, 2002, stated that the FDA had 60 kava-related AERs since 1998 (Burros, 2002). ABC contacted the FDA and was told the agency has only 26 AERs related to kava-containing products, with only a few related to liver (Cianci, 2002). Fortunately, a story on January 22 in the *Washington Post* correctly reported the 26 cases (Packer-Tursman, 2002). A group of 25 AERs reflecting reports to the

FDA from March 1998 to August 2001 implicating products in which kava is an ingredient (some contain multiple ingredients, raising questions regarding the effects kava may have had on the reported adverse event) were obtained through the Freedom of Information Act process by AHPA President Michael McGuffin. Of these 25 reports, only four reported some type of liver disorder (McGuffin, 2002a).

So the question is how can one resolve the apparent discrepancy in the FDAs reports on kava, from the 35 on the FDAs website in November (including the "fX" reports), to the 25 obtained by AHPA in January; to the 60 reported by *The New York Times* in January 2002? The answer lies in the fact that the reports on the FDA website had not been updated since October 1998; that is, they are more than three years old with no additional revisions! And, to complicate matters more, the *Times* article included the 29 "fX" cases, even though the reporter had been told previously by this writer that the cases were not associated with kava and should not be listed on the FDA database under "kava".

Kava Safety and Precautions

The kava-liver safety issue comes as somewhat of a surprise to most industry members, health professionals, and consumers familiar with the history and clinical use of kava. There is little evidence in the scientific literature to suggest liver toxicity; and the herb has enjoyed safe use for centuries in Polynesia. A meta-analysis on clinical trials on the acetone-based kava extract from Germany does not mention liver toxicity as one of the adverse effects noted in clinical trials, concluding that kava appears to be a safe and effective remedy for

anxiety (Pittler and Ernst, 1999). In October, a Duke University clinical trial to assess the adverse effects profile of an American kava extract (KavaPure®, PureWorld, South Hackensack, New Jersey) found only insignificant elevations of liver enzymes in three of the 38 subjects in the trial (one already with elevated levels before the study began), concluding that kava is relatively safe (Connor *et al.*, 2001).

No one seems to be certain what's going on. Contamination has been ruled out as the products implicated come from various sources. No definitive mechanism explains the alleged toxicity although several are speculated. Polynesians blame the European extracts, saying that the traditionally used kava beverages do not produce liver problems. This assertion has not been proven scientifically. Some have suggested that the acetone solvent used to make the leading European kava extract may be at fault, but analysis of the case reports shows that five of the six most serious cases are related to ethanolic (alcohol) extracts. This writer cautions all concerned not to suggest that differences in products have any toxicological significance until all the evidence has been properly evaluated.

Because of the confusion and the potential seriousness of the issue, on December 20, 2001, the ABC issued a press release explaining the situation at the time and suggesting that the public adhere to the following cautions:

*Kava should not be used by anyone who has liver problems, or by anyone who is taking any drug products with known adverse effects on the liver, or anyone who is a regular consumer of alcohol.

* Since the reports so far are associated with chronic use, kava

should not be taken on a daily basis for more than four weeks (without the advice of a qualified professional).

* In addition, consumers should discontinue use if symptoms of jaundice (e.g. dark urine, yellowing of the eyes) occur.

* Consumers should consult their primary healthcare provider if they have a history of liver problems or suspect possible liver problems before using kava or continuing its use.

ABC precautions have been noted in *USA Today* and the Associated Press articles. ABC deemed these cautions reasonable and prudent, based on the information available at the time ABC issued the precautions (December). (The complete text, plus new information, can be viewed on ABC's website www.herbalgram.org. AHPA has issued similar information for consumers www.ahpa.org. AHPA retained a highly regarded professional toxicologist from a leading university to ascertain the nature of the relationship between kava consumption and liver problems (AHPA *et al.*, 2002). AHPA president Michael McGuffin was quoted as saying, "Despite the fact that the kava products under scrutiny are ones manufactured and sold in Europe, we believe that it is critical that kava's long history of safe use be re-affirmed by a review of the information." In February 2002, AHPA released a summary of this review, available on its website.

Despite the relatively good safety profile that kava has in the United States, these actions by the German and other European governments must be taken very seriously by members of the U.S. industry. Germany has led the world in clinical research and rational regulation of herbal medicines. If its regulators think

there's a problem, then this is something that the U.S. herb industry and the FDA must deal with carefully and forthrightly. What is becoming somewhat clear, however, is that kava is being anecdotally linked to reports of liver dysfunction without any confirming scientific evidence. An expert evaluation of the medical case reports and all relevant scientific literature is warranted to determine the extent of the problem and the necessary steps for the appropriate labeling and regulation of kava.

There are many issues to be reviewed and resolved on the kava situation. This is one of the most serious challenges ever experienced by the herb and dietary supplement community in recent history.

More information on this issue will be posted on ABC's website (www.herbalgram.org) as new developments arise.

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Enhancement by Dr: Carl Botefuhr, D.C. from www.kavakavafarm.com.

Resources

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Mark Blumenthal is the founder and executive director of the American Botanical Council in Austin, Texas, a non-profit organization, and is editor of its journal *HerbalGram* (www.herbalgram.org). He also served as senior editor of two books in English on the German Commission E Monographs, one of the world's most comprehensive considerations of herbal medicine, and is the senior editor of a new reference book of monographs for health professionals that has been accredited for pharmacy CE by TPA, *The ABC Clinical Guide to Herbs*. Blumenthal serve an adjunct associate professor of medicinal chemistry at the College of Pharmacy at UT-Austin where he teaches a course on "Herbs and Phyto-medicines in Today's Pharmacy."

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Continuing Education for Pharmacists

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Patient Counseling: Glaucoma; Part 1: The Disease

**J. Richard Wuest, R.Ph.,
Pharm.D.**
Professor of Pharmacy Practice
University of Cincinnati
Cincinnati, Ohio

and

Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology and
Toxicology
Ohio Northern University
Ada, Ohio

Goal. The goal of this lesson is to review the types of glaucoma, the anatomy and function of the eye as it relates to glaucoma, the causes of glaucoma and its treatment.

Objectives. At the conclusion of this lesson, successful participants should be able to:

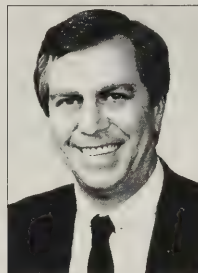
1. differentiate open-angle from angle-closure glaucoma;
2. exhibit knowledge of the anatomy and function of the eye as it relates to glaucoma; and
3. identify nondrug therapies of glaucoma.

Introduction

Glaucoma is a condition caused by a number of different diseases that



Gossel



Wuest

can lead to optic nerve damage and visual field loss. Most of these pathologies are characterized by elevated intraocular pressure (IOP), an important risk factor for the development of glaucoma. This increased pressure within the eye is the cause of damage to the optic nerve. As the optic nerve deteriorates due to increased pressure, the individual gradually loses peripheral vision, the ability to see to the side. In time, central vision may also decline as well. Left untreated, glaucoma may eventually lead to total blindness.

Glaucoma is a leading cause of irreversible vision loss in the U.S., and the second most common cause of blindness in this country after diabetes mellitus. Glaucoma affects about three million Americans, half of whom do not know they have the condition because of its lack of early, obvious symptoms. Individuals with glaucoma are, therefore, usually unaware that they have the problem until it is detected on routine examination and serious loss of vision has occurred. About 80,000 of the Americans diagnosed with glaucoma are legally blind. Glaucoma accounts for over 4.5 million visits to physicians each year.

It is important for everyone to be concerned about glaucoma and its potential outcome. IOP of 25-35mm

Hg and higher may cause detachment of the cornea, cataract formation, and atrophy of the optic nerve and retina. Early detection and treatment are the only means to prevent vision impairment and blindness for most patients. It is recommended that individuals under age 45 with no risk factors for glaucoma have an eye exam every four years; with risk factors, every two years. For individuals 45 years of age and older, the recommendation for those with no risk factors is every two years; with risk factors, the recommendation for a comprehensive eye exam is every year. Risk factors for glaucoma are listed in Table 1 and a glossary of vision terms in Table 2.

Types of Glaucoma

Increased IOP can result primarily from either increased production or decreased outflow of aqueous humor. More than 40 types of glaucoma have been identified, but most fall into the following types: **primary open-angle, angle-closure, and congenital**; and **secondary glaucoma**.

Primary open-angle glaucoma is the most common form of the disease. It develops slowly and painlessly due to improper drainage of the normal eye fluid (aqueous humor). This causes pressure to build up in the eye. This form is called open-angle because the angle of the anterior chamber, between the cornea and iris (discussed later), is open to aqueous humor outflow, although the outflow may be somewhat decreased. It accounts for 60-70 percent of all glaucoma cases, about two million individuals in the U.S. It often goes undetected for

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Table 1
Risk Factors for Glaucoma

- **Age** – the chance of developing glaucoma increases after the age of 40, especially in individuals who have not had regular eye examinations. The disease is NOT considered a normal part of aging.
- **Family history of glaucoma** – individuals with an immediate relative (such as parent or sibling) with glaucoma have a 20 percent chance of also developing the disease.
- **Abnormally high intraocular pressure**
- **African or Asian descent** - African-Americans are three to four times more likely than Caucasians to develop glaucoma, and six times more likely to suffer permanent blindness as a result of the disease. Asian Americans are also more susceptible to glaucoma than Caucasians.
- **Diabetes mellitus** – individuals with diabetes have a three times greater risk for developing glaucoma than people who do not have the disease.
- **Regular, long-term corticosteroid use** – the risk for developing secondary glaucoma increases if one takes systemic corticosteroids, inhales corticosteroids for asthma, or applies ophthalmic corticosteroids for prolonged periods of time.
- **Previous eye injury** – past injuries to the eye or eye surgery may trigger secondary glaucoma. Any type of ocular inflammation, especially uveitis, may increase the risk.

years. Individuals with this type of glaucoma gradually lose peripheral vision until only a narrow section of the visual field remains clear.

Primary glaucoma tends to affect both eyes, although symptoms may appear in just one eye initially. Other symptoms include sensitivity to glare and trouble differentiating varying shades of light and dark. It is more likely to develop as one ages, suggesting that primary glaucoma may result from aging cells that do not drain aqueous humor as efficiently.

Normal-tension glaucoma, another form of primary open-angle

glaucoma, is characterized by severe optic neuropathy in the absence of abnormally high IOP. Patients with normal-tension glaucoma have pressures within the normal range, often in high normal values.

Angle-closure glaucoma affects about 10 percent of individuals with glaucoma. It occurs suddenly, due to pupillary blockage of aqueous humor outflow, possibly causing an acute attack with dramatic symptoms that require immediate attention. Some individuals may experience preliminary warnings weeks or even months before a severe attack. Attacks usually occur in the evening when the light is dim and pupils are dilated. Pain may be very severe and cause vomiting. Other signs and symptoms include blurred vision (usually in just the involved eye), halos appearing around lights, reddening of the affected eye, morning headache, and swollen or cloudy corneas.

People with angle-closure glaucoma have a very narrow drainage angle where the aqueous fluid drains between the iris and cornea. When pupils become intensely dilated, the outflow may end completely, causing a sudden increase in pressure and triggering an acute attack. This may be precipitated by medications (anti-histamines, tricyclic antidepressants, ophthalmic drops used to dilate pupils), darkness or dim light, or emotional stress. In some individuals, the narrow drainage angle may simply be a structural abnormality. In others, it may be due to aging. Generally, as one ages, the lens in the eye gradually becomes larger, pushing the iris forward and narrowing the drainage angle between the iris and cornea.

Congenital glaucoma is present at birth and affects a much smaller number of individuals. Signs and symptoms, such as eyes that seem cloudy, are often watery or teary, or are sensitive to light, may not appear until the infant is a few months old.

Secondary glaucoma results

from trauma, chronic corticosteroid use, or disease. Symptoms of this type of glaucoma vary, depending on the cause.

Secondary glaucoma occurs in individuals who have other ocular afflictions, and may be caused by any of the following: certain medical conditions (people with diabetes are especially at high risk); medications (especially corticosteroids that increase pressure in the eye – including inhaled, oral or topically applied ophthalmic preparations); and physical injury. Severe trauma to the eye or local tumors can increase IOP, leading to secondary glaucoma.

Eye Anatomy

The eyes are part of a complex process that transforms light waves into images in the brain. This process begins when light enters the eye through a clear tissue called the cornea. Behind the cornea, the iris (the colored portion of the eye) regulates the amount of light that passes through to the crystalline lens. The lens then focuses this light onto the retina, a thin, transparent membrane in the back portion of the eye. The retina translates this light into signals that are sent to the optic nerve, a bundle of more than one million nerve fibers. The optic nerve transmits these signals to the brain where they are interpreted as images. A healthy optic nerve is necessary for good vision.

Between the cornea and the lens, a clear nutrient-rich fluid called the aqueous humor nourishes the internal structures of the eye. This fluid is secreted by the ciliary processes and circulates from behind the iris through the pupil, the dark opening in the center of the eye, into a small space in the front of the eye called the anterior chamber. The aqueous humor also exerts constant IOP that helps maintain the shape of the eye.

Normal IOP is between 10 and 20mm Hg. IOP is maintained via a balance between fluid secretion and

Table 2
Glossary of Vision Terms

Anterior Chamber. Space in front of the iris and behind the cornea
Aqueous Humor. Clear, watery fluid that flows between and nourishes the lens and the cornea; secreted by the ciliary processes
Canal of Schlemm. Passageway for aqueous humor to leave the eye
Choroid. The vascular layer that nourishes the retina; part of the uvea
Ciliary Body. Middle layer of the eyeball containing ciliary muscles and processes
Ciliary Muscles. Enable the lens to change shape for focusing
Ciliary Processes. Extensions or projections of the ciliary body that secrete aqueous humor
Conjunctiva. Thin, moist tissue (membrane) that lines the inner surfaces of the eyelids and the outer surface of the sclera
Cornea. Outer, transparent, dome-like structure that covers the iris, pupil, and anterior chamber; part of the eye's focusing system
Fundus. Interior lining of the eyeball, including the retina, optic disc, and macula; portion of the inner eye that can be seen during an eye examination by looking through the pupil
Intraocular Pressure (IOP). Pressure exerted by aqueous humor
Iris. Colored ring of tissue suspended behind the cornea and immediately in front of the lens; regulates the amount of light entering the eye by adjusting the size of the pupil
Lens. Transparent, double convex (outward curve on both sides) structure suspended between the aqueous and vitreous humor; helps to focus light on the retina
Optic Nerve. Bundle of over one million nerve fibers that carry visual messages from the retina to the brain
Posterior Chamber. Space between the back of the iris and the front face of the vitreous; filled with aqueous fluid
Pupil. Adjustable opening at the center of the iris that allows varying amounts of light to enter the eye
Retina. Light-sensitive layer of tissue that lines the back of the eyeball; sends visual messages through the optic nerve to the brain
Sclera. White, outer layer (coat) of the eyeball; with the cornea, it protects the entire eyeball
Trabecular Meshwork. Spongy, mesh-like tissue near the front of the eye that allows aqueous humor to flow to Schlemm's canal then out of the eye through ocular veins
Uvea, Uveal Tract. Middle coat of the eyeball, consisting of the choroid in the back of the eye and the ciliary body and iris in the front of the eye
Vitreous Humor. Transparent, colorless mass of gel that lies behind the lens and in front of the retina

fluid outflow. Healthy eyes constantly produce aqueous humor. To keep this from accumulating in the eye, the fluid flows to the periphery and drains primarily through the trabecular meshwork. This drainage occurs in a "drainage angle" located at the point where the iris and cornea meet. The excess fluid then flows into a channel (canal of Schlemm) and finally into a system of small veins that return the fluid to the blood.

When the drainage angle does not function properly, the aqueous humor accumulates and exerts pressure on another fluid, the vitreous humor, located behind the

lens. The increased pressure within the vitreous humor presses on the fibers of the optic nerve, slowly damaging them. The resulting optic nerve atrophy is clinically characterized by excavation and cupping of the optic nerve, indicating a loss of optic nerve axons, with a gradual loss of vision.

Screening and Diagnosis

Detection of glaucoma is best accomplished through a comprehensive eye examination. This exam should include assessment of the family history, measurement of visual acuity and IOP, examination

of the retina and optic nerve through dilated pupils, and evaluation of the visual field. Individuals thought to have glaucoma should receive appropriate follow-up care and management.

A simple, painless testing procedure known as tonometry can signal the presence of glaucoma. Air-puff tonometry measures the pressure within the eyeball. This is achieved by measuring the amount of force needed to indent the eye with a rapid puff of air. A high pressure reading does not necessarily mean that one has glaucoma since it is possible to have a damaged optic nerve in the presence of normal IOP. If the pressure is high, an ophthalmologist can perform additional tests to help determine whether a person has glaucoma. Because of variations in what constitutes "normal" IOP for each individual, tonometry alone is not sufficient to assure a truly accurate diagnosis of glaucoma.

Applanation tonometry uses a device usually fitted to a slit lamp, a common instrument for eye examination. For this test, the eyes are anesthetized and the tonometer is placed directly on the eye. The pressure readings from this test are extremely accurate.

An ophthalmoscope is used to examine the back of the eye (fundus) and check the condition of the fibers in the optic nerve. Damaged fibers may appear asymmetrical or pale in color. A damaged optic nerve may indicate the beginning of glaucoma.

Glaucoma generally decreases peripheral vision (the ability to see to the side). In a visual field test (perimetry), the patient watches a monitor with flickering lights to measure the size of the visual field. Any changes in peripheral vision indicate potential optic nerve damage.

An ophthalmologist may use an instrument known as a gonioscope to view the anterior chamber angle directly to distinguish between primary open-angle and angle-closure glaucoma. This instrument allows for inspection of the drainage

angle between the cornea and the iris, and permits a direct view of the anterior chamber angle.

Treatment

Glaucoma treatment may not be necessary if the IOP is only slightly elevated with no damage to the optic nerve. The physician may choose to monitor the condition with regular eye exams. If, however, there are any signs of optic nerve damage, treatment can help slow progression of the disease. It is not currently possible to reverse the damage that has already occurred in patients with glaucoma.

Topical medications in the form of ophthalmic drops are typical therapy for the treatment of glaucoma. When medications aren't effective or well-tolerated, surgery may be an option. Surgery, however, does not cure glaucoma, but can greatly improve the prognosis. As a result, individuals may need to continue with medications even after surgery.

Laser surgery, also called argon laser trabeculoplasty (ALT), is the most common laser treatment for open-angle glaucoma. It is used to shrink part of the meshwork of the eye's drainage angle. Performed under local anesthesia, laser surgery requires only minutes to perform. It involves use of a high-energy beam of light to make 50-100 tiny, evenly-spaced lesions on the inner surface of the trabecular meshwork that open the drainage area inside the eye. This permits other areas of the meshwork to stretch, allowing for improved outward drainage of the aqueous fluid and reduced IOP.

ALT is associated with reduced side effects and complications compared to traditional surgery. However, success rates do vary. It has been estimated that ALT will defer other surgical interventions for an average of five years in about 35 percent of patients treated. It may benefit those who are noncompliant with medication, or those concerned with side effects or cost. Because of the risk for surgical complications,

ophthalmologists reserve surgery for those individuals not well controlled by medication. Complications include the development of cataracts, endophthalmitis (inflammation of tissues within the eyeball), vitreous hemorrhage, and chronic macular edema. It is not effective in patients under age 40 or in patients with uveitis. National Eye Institute-supported research has shown that laser surgery is a safe and effective alternative to ophthalmic drops as treatment for newly diagnosed glaucoma.

Trabeculectomy (also called glaucoma filtration surgery) is the laser surgical procedure used to create a new drainage pathway for fluid in the white part of the eye (sclera). It is performed under local anesthesia to make a scleral flap to allow easier outflow of aqueous humor. This surgery is often used for the 40-50 percent of patients whose glaucoma cannot be controlled with other medical treatments. This procedure may cause complications such as cataract formation and temporary blurred vision.

The use of antimetabolites such as 5-fluorouracil and mitomycin, during or after trabeculectomy, improves the success of the surgery. Antimetabolites may inhibit fibroblast proliferation and excessive deposits of collagen at the wound site, preventing closure of the filtration site. Treatment may consist of 5-fluorouracil (5-FU) administered in 5mg subconjunctival injections for up to two weeks after the surgical procedure. Topical 5-FU may also be used by some surgeons. Mitomycin C (0.2-0.4mg/mL) is applied topically to the scleral flap in a single application prior to creating the filtration channel.

The use of drainage implants may be an option when other treatments have failed. In this procedure, a small silicon tube is inserted in the eye to help drain aqueous fluid. A procedure called an iridotomy is used to treat acute glaucoma after medications are used to quickly reduce IOP following an attack. This emergency operation

uses a laser to create a drainage hole in the iris.

Although IOP for low-pressure glaucoma is normal, treatment with standard anti-glaucoma medications seems to slow the progression of the disease.

In the early 1970s, studies reported that when marijuana was smoked, it lowered IOP in people with normal pressure and also in those with glaucoma. The National Eye Institute supported research from 1978-1984 in an effort to determine whether marijuana, or drugs derived from marijuana, might be effective as a glaucoma treatment. These studies demonstrated that some derivatives of marijuana lowered IOP when administered orally, IV, or by smoking, but not when applied topically to the eye. However, none of these studies demonstrated that marijuana or any of its components could safely and effectively lower IOP more efficiently than other drugs currently available. It was determined that simply lowering IOP does not necessarily control the disease. Also, some serious side effects, specifically increased heart rate and decreased blood pressure, were noted with the use of marijuana.

It is not known at this time whether the use of marijuana offers any advantages over currently available glaucoma treatments or if it is useful when combined with standard therapies. The National Eye Institute has gone on record as ready to evaluate any well-designed studies for treatment of glaucoma, including those involving the use of marijuana.

Part 2 of this two-part series will review medical treatment of glaucoma.

Continuing Education Quiz

This month's questions are taken from the article on "Patient Counseling: Glaucoma; Part 1: The Disease." Circle your answers to the following questions and mail the entire page to Maryland Pharmacist CE, 650 W. Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members \$ 10.00). The completed quiz for this issue must be received by 9/15/04. A continuing education certificate for one and one-half contact hours (0.15 CEUs) will be mailed to you within six to eight weeks. Please type or print clearly. ACPE# 129-144-01-009-H01.

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The Maryland Pharmacy Continuing Education Coordinating Council and the Ohio Pharmacists Foundation are both approved providers of continuing pharmaceutical education for pharmacists by the American Council on Pharmaceutical Education.



1. As the optic nerve deteriorates in patients with glaucoma, the first field of vision that the individual loses is:

- a. central vision.
- b. peripheral vision.

2. The most common form of glaucoma that affects patients is:

- a. angle-closure.
- b. congenital.
- c. primary open-angle.
- d. secondary open-angle.

3. Which of the following groups of Americans is most susceptible to developing glaucoma?

- a. Caucasians
- b. African-Americans
- c. Polynesian-Americans
- d. Asian-Americans

4. The type of glaucoma that occurs suddenly and requires immediate attention is:

- a. angle-closure.
- b. congenital.
- c. primary open-angle.
- d. secondary open-angle.

5. Secondary glaucoma results from all of the following causes EXCEPT:

- a. disease.
- b. trauma.
- c. corticosteroid use.
- d. birth defects.

6. Normal intraocular pressure (IOP) values range from:

- a. 1 to 9mm Hg.
- b. 10 to 20mm Hg.
- c. 25 to 35mm Hg.
- d. 40 to 50mm Hg.

7. Aqueous humor is secreted by the:

- a. iris
- b. pupil.
- c. ciliary processes.
- d. canal of Schlemm.

8. The transparent, colorless mass of gel that lies between the lens and the front of the retina is the:

- a. aqueous humor.
- b. fundus.
- c. sclera.
- d. vitreous humor.

9. The instrument used for eye exams that is usually fitted to a slit lamp and placed directly on the anesthetized eye is the:

- a. gonioscope.
- b. perimeter.
- c. ophthalmoscope.
- d. tonometer.

10. The laser surgery used for open-angle glaucoma that opens the drainage area by making evenly spaced lesions is performed on the:

- a. canal of Schlemm.
- b. optic nerve.
- c. trabecular meshwork.
- d. ciliary processes.

CORRECTION: The correct ACPE number for Patient Counseling: Management of Sore Throat which appeared in the Jan./Feb./Mar. 2002 issue of the *Maryland Pharmacist* is 129-144-01-011-H01.



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Pharmacist Licensure Examination

For the results of the Pharmacist Licensure examination visit the Maryland Board of Pharmacy's website at: www.dhmd.state.md.us/pharmacyboard/pharmlic/0600rost.htm. The results are updated every Friday.



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CLARINEX® (desloratadine) TABLETS

Brief Summary (For full Prescribing Information, see package insert.)

INDICATIONS AND USAGE: Allergic Rhinitis: CLARINEX Tablets 5 mg are indicated for the relief of the nasal and non-nasal symptoms of allergic rhinitis (seasonal and perennial) in patients 12 years of age and older.

Chronic Idiopathic Urticaria: CLARINEX Tablets are indicated for the symptomatic relief of pruritus, reduction in the number of hives, and size of hives, in patients with chronic idiopathic urticaria 12 years of age and older.

CONTRAINDICATIONS: CLARINEX Tablets 5 mg are contraindicated in patients who are hypersensitive to this medication or to any of its ingredients, or to loratadine.

PRECAUTIONS: Carcinogenesis, Mutagenesis, Impairment of Fertility: The carcinogenic potential of desloratadine was assessed using loratadine studies. In an 18-month study in mice and a 2-year study in rats, loratadine was administered in the diet at doses up to 40 mg/kg/day in mice (estimated desloratadine and desloratadine metabolite exposures were approximately 3 times the AUC in humans at the recommended daily oral dose) and 25 mg/kg/day in rats (estimated desloratadine and desloratadine metabolite exposures were approximately 30 times the AUC in humans at the recommended daily oral dose). Male mice given 40 mg/kg/day loratadine had a significantly higher incidence of hepatocellular tumors (combined adenomas and carcinomas) than concurrent controls. In rats, a significantly higher incidence of hepatocellular tumors (combined adenomas and carcinomas) was observed in males given 10 mg/kg/day and in males and females given 25 mg/kg/day. The estimated desloratadine and desloratadine metabolite exposures of rats given 10 mg/kg of loratadine were approximately 7 times the AUC in humans at the recommended daily oral dose. The clinical significance of these findings during long-term use of desloratadine is not known.

In genotoxicity studies with desloratadine, there was no evidence of genotoxic potential in a reverse mutation assay (*Salmonella/E. coli* mammalian microsome bacterial mutagenicity assay) or in two assays for chromosomal aberrations (human peripheral blood lymphocyte clastogenicity assay and mouse bone marrow micronucleus assay).

There was no effect on female fertility in rats at desloratadine doses up to 24 mg/kg/day (estimated desloratadine and desloratadine metabolite exposures were approximately 130 times the AUC in humans at the recommended daily oral dose). A male specific decrease in fertility, demonstrated by reduced female conception rates, decreased sperm numbers and motility, and histopathologic testicular changes, occurred at an oral desloratadine dose of 12 mg/kg in rats (estimated desloratadine exposures were approximately 45 times the AUC in humans at the recommended daily oral dose). Desloratadine had no effect on fertility in rats at an oral dose of 3 mg/kg/day (estimated desloratadine and desloratadine metabolite exposures were approximately 8 times the AUC in humans at the recommended daily oral dose).

Pregnancy Category C: Desloratadine was not teratogenic in rats at doses up to 48 mg/kg/day (estimated desloratadine and desloratadine metabolite exposures were approximately 210 times the AUC in humans at the recommended daily oral dose) or in rabbits at doses up to 60 mg/kg/day (estimated desloratadine exposures were approximately 230 times the AUC in humans at the recommended daily oral dose). In a separate study, an increase in pre-implantation loss and a decreased number of implantations and fetuses were noted in female rats at 24 mg/kg (estimated desloratadine and desloratadine metabolite exposures were approximately 120 times the AUC in humans at the recommended daily oral dose). Reduced body weight and slow righting reflex were reported in pups at doses of 9 mg/kg/day or greater (estimated desloratadine and desloratadine metabolite exposures were approximately 50 times or greater than the AUC in humans at the recommended daily oral dose). Desloratadine had no effect on pup development at an oral dose of 3 mg/kg/day (estimated desloratadine and desloratadine metabolite exposures were approximately 7 times the AUC in humans at the recommended daily oral dose). There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, desloratadine should be used during pregnancy only if clearly needed.

Nursing Mothers: Desloratadine passes into breast milk, therefore a decision should be made whether to discontinue nursing or to discontinue desloratadine, taking into account the importance of the drug to the mother.

Pediatric Use: The safety and effectiveness of CLARINEX Tablets in pediatric patients under 12 years of age have not been established.

Geriatric Use: Clinical studies of desloratadine did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. (see **CLINICAL PHARMACOLOGY – Special Populations**).

Information for Patients: Patients should be instructed to use CLARINEX Tablets as directed. As there are no food effects on bioavailability, patients can be instructed that CLARINEX Tablets may be taken without regard to meals. Patients should be advised not to increase the dose or dosing frequency as studies have not demonstrated increased effectiveness at higher doses and somnolence may occur.

ADVERSE REACTIONS: Allergic Rhinitis: In multiple-dose placebo-controlled trials, 2,834 patients received CLARINEX Tablets at doses of 2.5 mg to 20 mg daily, of whom 1,655 patients received the recommended daily dose of 5 mg. In patients receiving 5 mg daily, the rate of adverse events was similar between CLARINEX and placebo-treated patients. The percent of patients who withdrew prematurely due to adverse events was 2.4% in the CLARINEX group and 2.6% in the placebo group. There were no serious adverse events in these trials in patients receiving desloratadine. All adverse events that were reported by greater than or equal to 2% of patients who received the recommended daily dose of CLARINEX Tablets (5.0 mg once-daily), and that were more common with CLARINEX Tablet than placebo, are listed in Table 5.

Table 5

Incidence of Adverse Events Reported by $\geq 2\%$ of Allergic Rhinitis Patients in Placebo-Controlled, Multiple-Dose Clinical Trials

Adverse Experience	CLARINEX Tablets 5 mg (n=1,655)	Placebo (n=1,652)
Pharyngitis	4.1%	2.0%
Dry Mouth	3.0%	1.9%
Myalgia	2.1%	1.8%
Fatigue	2.1%	1.2%
Somnolence	2.1%	1.8%
Dysmenorrhea	2.1%	1.6%

The frequency and magnitude of laboratory and electrocardiographic abnormalities were similar in CLARINEX and placebo-treated patients.

There were no differences in adverse events for subgroups of patients as defined by gender, age, or race.

Chronic Idiopathic Urticaria: In multiple-dose, placebo-controlled trials of chronic idiopathic urticaria, 211 patients received CLARINEX Tablets and 205 received placebo. Adverse events that were reported by greater than or equal to 2% of patients who received CLARINEX Tablets and that were more common with CLARINEX than placebo were (rates for CLARINEX and placebo, respectively): headache (14%, 13%), nausea (5%, 2%), fatigue (5%, 1%), dizziness (4%, 3%), pharyngitis (3%, 2%), dyspepsia (3%, 1%), and myalgia (3%, 1%).

The following spontaneous adverse events have been reported during the marketing of desloratadine: tachycardia, and rarely hypersensitivity reactions (such as rash, pruritus, urticaria, edema, dyspnea, and anaphylaxis), and elevated liver enzymes including bilirubin.

DRUG ABUSE AND DEPENDENCE: There is no information to indicate that abuse or dependency occurs with CLARINEX Tablets.

OVERDOSAGE: Information regarding acute overdosage is limited to experience from clinical trials conducted during the development of the CLARINEX product. In a dose ranging trial, at doses of 10 mg and 20 mg/day somnolence was reported.

Single daily doses of 45 mg were given to normal male and female volunteers for 10 days. All ECGs obtained in this study were manually read in a blinded fashion by a cardiologist. In CLARINEX-treated subjects, there was an increase in mean heart rate of 9.2 bpm relative to placebo. The QT interval was corrected for heart rate (QT_c) by both the Bazett and Fridericia methods. Using the QT_c (Bazett) there was a mean increase of 8.1 msec in CLARINEX-treated subjects relative to placebo. Using QT_c (Fridericia) there was a mean increase of 0.4 msec in CLARINEX-treated subjects relative to placebo. No clinically relevant adverse events were reported.

In the event of overdose, consider standard measures to remove any unabsorbed drug. Symptomatic and supportive treatment is recommended. Desloratadine and 3-hydroxydesloratadine are not eliminated by hemodialysis.

Lethality occurred in rats at oral doses of 250 mg/kg or greater (estimated desloratadine and desloratadine metabolite exposures were approximately 120 times the AUC in humans at the recommended daily oral dose). The oral median lethal dose in mice was 353 mg/kg (estimated desloratadine exposures were approximately 290 times the human daily oral dose on a mg/m² basis). No deaths occurred at oral doses up to 250 mg/kg in monkeys (estimated desloratadine exposures were approximately 810 times the human daily oral dose on a mg/m² basis).

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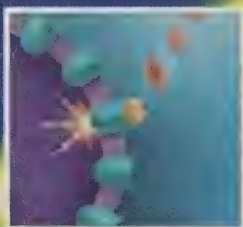
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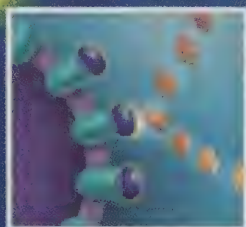
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In chronic idiopathic urticaria, the most commonly reported adverse events included headache (14%, placebo 13%), nausea (5%, placebo 2%), and fatigue (5%, placebo 1%).

Please see brief summary of Prescribing Information on adjacent page.

MARYLAND Pharmacist

VOLUME 78 NO. 3

President's Address

*"FUNDS—Fundraising, Unification,
Numbers, Direction and Shadowing"*

120th Annual Convention

"In Pictures"

Putting the Brakes on Abuse

"How the Team Takes Action"



*Paul Holly, P.D.
MPhA's 2002-2003 President*

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The Official Publication of the Maryland Pharmacists Association

President's Address 5

"FUNDS—Fundraising, Unification, Numbers,
Direction and Shadowing"

Director's Column 9

"Medicaid Prescription Drug Program"

The MPhA Foundation 17

"Pledge Form"

The 120th Annual Convention 20

"In Pictures"

What Would Einstein Do? 23

"Taking an Elementary Approach to Solving
Workplace Issues"

Do You Remember? 25

"Older than Dirt Quiz"

Putting the Brakes on Abuse 27

"How the Team Takes Action"

Continuing Education 34

Patient Counseling: " Glaucoma; Part 2:
Treatment"

Advertiser's Index

Giant	30
Mayer & Steinberg	9
McKessonHBOC	4
MPhA Foundation	17
MVCP	10
PEAC	14
Pharmacists Mutual	40
PharmaSTAT	14
RPh on the go	30
Safeway	30
The Black Eyed Susan	7
Walgreens	30

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**Paul R. Holly, P.D.
President**

FUNDS – Fundraising, Unification, Numbers, Direction and Shadowing

Dear MPhA Members: Below is the speech I gave as my President's Address at the 120th Annual Awards banquet at the Annual Convention, June 8 –11, 2002 in Ocean City, Maryland. There are a number of goals I have set for this year and they can easily be remembered by the acronym FUNDS.

I wish to express my sincere thanks to each and every member of the Maryland Pharmacists Association for your vote of confidence in electing me to serve as the 118th President of this association. Even though we are celebrating our 120th year, in the early history of MPhA, there were two Presidents who served two years each, J. J. Thomsen 1882 and 1883, and John Briscoe, M.D. 1892 and 1893. As I look back over the list of the past Presidents, and recognize how their leadership has played such an important part in shaping Pharmacy in Maryland, it humbles me to have my name listed among these outstanding pharmacists. I am deeply honored to represent you, the membership of the Maryland Pharmacists Association.

As some of you may know, I am a transplant from West Virginia, and will always be a Mountaineer at heart, but I consider Maryland my home. By the way, are you aware that two of the last three Presidents of the Maryland Pharmacists Association have been Mountaineers? Of course I am referring to Murhl Flowers, President from 2000 – 2001 and now myself.

I mentioned that I consider Maryland my home and that's because, except for four and a half years, I have lived in Maryland for the past 32 years. I moved to Maryland to accept a position with People's Drug Stores in Laurel when I graduated from West Virginia University School of Pharmacy in 1970. Ironically, I met the father—Leonard DeMino, a supervisor with Peoples—of a Past President. Who would have ever thought that I would come to know, and through association involvement, work with and become friends with his son, Joe DeMino, 30 years later? Joe was President 1999 – 2000.

While I started my career in retail, I have been fortunate to practice Pharmacy in a variety of settings. After three years in retail, and not getting to spend time with my then new born daughter, I moved to a hospital setting with the Veterans Administration which held the promise of more reasonable hours. This practice setting offered both inpatient and outpatient opportunities and led to a new challenge, which was to design, and open, a new outpatient pharmacy center on the campus of Ohio State University. Other tours of duty with the VA included stops in Indiana and Virginia.

After returning to Maryland in 1983, I continued to work as a Veterans Administration pharmacist at Fort Howard VA Medical Center. In 1985, a new challenge awaited me and I began designing and opening pharmacies for a former Baltimore food chain, Valu Food. From this, I returned briefly to the clinical setting in a small independent medical center. Again, opportunity knocked and I became an independent pharmacy store owner. In this venture, it was my distinct pleasure of meeting, partnering with, and still counting among my closest friends, Past President Mark Levi, and Bernie Weisman, whom we all keep in our prayers daily. I wish he could be here tonight, as Mark is, to share this moment with me.

It is also interesting to note that the person from whom we purchased this store, Edwards and Anthony in Dundalk, was another Past President. He was instrumental in the passage of House Bill 781, the Drug Therapy Management bill which allows a physician, pharmacist, and patient to enter into a contract to improve the health of the patient by allowing the pharmacist to use real patient skills. This tremendous leader in Maryland Pharmacy today is George Voxakis.

Mark, Bernie and I had the business together for seven years, and after selling the business, I accepted a position as Manager of an independent pharmacy in a Johns Hopkins facility. The owner of Tuxedo Pharmacy at Greenspring Station, another Past President, Arnold Davidov, is the person who first invited me to a local Alpha Zeta Omega Pharmacy Fraternity meeting and sparked my interest in association work. Another Past

President, who is currently serving as our Executive Director, Howard Schiff, nominated me to fill an MPhA Board of Trustees vacancy. Little did I know then, that my continuous involvement over the years would lead to this evening.

Through the variety of wonderful opportunities I have had to practice Pharmacy, I have worked with, and become friends with numerous outstanding individuals. To name them this evening would take a long time and I might inadvertently overlook someone. Many of them are here this evening and you know who you are. I thank you for your support and friendship over the years. Pharmacy has been good to me and I am thankful for the opportunity to give back.

While I count among my blessings the friends I have met through Pharmacy, I would not be here before you tonight were it not for the support and love of my family. They are my Pride and Joy. First, there is Joy, who is my only sibling, my sister Joy, and my brother-in-law, Tom who are here from Michigan with their three children, (now young adults) Camden, Chasen and Holly. Next comes my PRIDE, my daughter, Heather, who, as I mentioned earlier, although she didn't know it at the time, was instrumental in helping me make a choice which ultimately let to varied career practices for the past 31 years. And last, but not least, I is the person who is my best friend, my soul mate, my lover, and my bride of almost 23 years, Jeanne-Marie. I appreciate your encouragement and support and love that you have given me over the years.

Thank you for allowing me to share my family and my background with you. As you can tell, family and friends are very important to me. I would now like to focus on what I hope to accomplish, with your Board of Trustees and your support, over the next year.

Having served in a variety of roles prior to being elected as President, I have had the opportunity to see the goals of our association achieved and new ones set. As Pharmacy continues to change, we constantly face new challenges that require new ways of meeting them, setting new goals, and growing professionally. There are a number of goals that I have set for this year and they can be easily be remembered by the acronym FUNDS.

To many of you, this will not come as a surprise but the "F" stands for Fund raising. I would like to increase our fund raising efforts dramatically. Over the past four years, I have been actively involved in fund raising on behalf of the MPhA Foundation. Initial activities were begun on a small scale with raffles, silent and live auctions held at previous conventions and mid-year meetings, and the selling of pill tiles. These, as some of you have called "nickel and dime" efforts, have raised over \$47,000 for the Foundation since November of 1998, with nearly \$10,000 coming from the sale of Pill Tiles

alone. (I really appreciate the support of those of you who early on purchased Pill Tiles and thought you were purchasing Pill Towels. It was Mel Rubin who brought to my attention that he thought I was suggesting Pill Towels instead of Pill Tiles. My West Virginia English can not be found in Websters!)

New at this convention, golf shirts with the MPhA logo are available. Who knows what next year will bring. I can't wait – can you? While these items will continue to be offered over the next year, we have also taken a more aggressive approach. This includes corporate and private donations to the Foundation, amounting to more than a nickel and dime. If you have not made a commitment, look for pledge forms coming soon in our quarterly journal and in your mailboxes. At this time I wish to thank Mayer Handleman for his efforts on behalf of the Foundation. In a large part, through Mayer's efforts, we have pledges from members, past presidents, and current MPha Board of Trustee's members for over \$40,000. Mayer has co-chaired the Fundraising Committee this past year with Marty Mintz. This "major" fundraising effort was kicked off at a reception held in the Kelly building after our last mid-year meeting. This exciting fund raising program provides us with the opportunity to make a difference for Maryland Pharmacy by:

- upgrading facilities at the Kelly Building to accommodate meetings and events;
- displaying of two museums in a manner that reflects Pharmacy's history and pride;
- providing a scholarship program for state residents at the University of Maryland School of Pharmacy; and
- educating the public through a variety of public service programs.

A separate Board of Directors for the MPhA Foundation will be named within the next sixty days. This Board will provide direction for most of the future fund raising activities.

The next letter in the acronym FUNDS is "U" which stands for Unite. Of course, this Board of Trustees will continue to support the Maryland Pharmacy Coalition. This coalition was formed to stress the need to coordinate efforts among all facets of Pharmacy and to provide a strong unified voice. There are but a few states that have developed this type of partnership between the various practice settings. We are very proud of the efforts of the founding fathers of this Coalition, many of whom are MPhA members, including past presidents Murhl Flowers and Mark Sanford and the Chair for MPC this year is your First Vice President, Richard Baylis.

Going back to the acronym FUNDS, the "N" stands for Numbers, as in *increased* membership. Another

priority of the Board this year is membership. Membership decline in recent years, in my opinion, reflects apathy of pharmacists practicing in the State and their lack of concern about the future of the profession. Although a slight increase in membership occurred this past year, MPhA must find innovative ways to attract new members and to retain existing members.

The current membership drive of "Each One Reach One" has met with limited success, resulting in almost an 10% increase over the previous year. In order to be a viable voice for Pharmacy, MPhA must gain active members representative of all practice settings. I would like MPhA to consider conducting a survey, or focus groups, to determine why existing members are members and why non-members do not join. The results of this research will better assist us in planning future membership programs and activities.

At the recent University of Maryland School of Pharmacy Alumni banquet to honor this year's Pharmacy graduates as well as acknowledge the class that graduated 50 years ago, Executive Director Schiff in his remarks, offered new graduates free membership in MPhA for the remaining months of this year.

The "D" in the word FUNDS stands for Direction. I would like to suggest and encourage the active participation of the Past-Presidents Council. Where else can we find such valuable experience and insight into Pharmacy of the past, present and the creation of new programs for the future? I am suggesting that the Past-Presidents Council meet every other month with the Executive Board to provide guidance and input to the Association's direction.

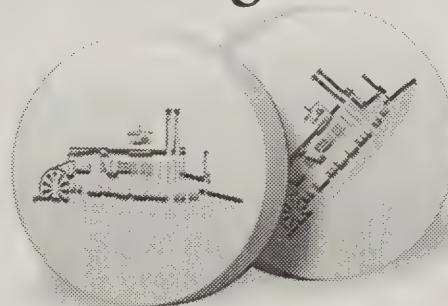
The last letter, "S" in the word FUNDS stands for Shadowing as in job shadowing and mentorship. I would like to promote the Pharmacy profession through the development of a mentoring/job shadowing program. This effort could be done by MPhA or possibly in partnership with the Maryland Pharmacy Coalition (MPC). Here is also an excellent opportunity for EPIC Pharmacies and CARE Drugs to be involved, along with ASCP and MSHP. The best time for this activity would be during National Pharmacy Week, held in October each year. MPC is currently planning major promotional events during this week. To emphasize the importance of such a program, think for a moment as to what or who influenced you to become a pharmacist. I recently had the experience of having two students shadow me for the day. One was in middle school and the other in high school. Both said they did not know that Pharmacy was so varied. Their previous impression was of someone who stands on their feet all day and counts pills. They had no idea of the interaction with other health professionals, consultations with patients or the amount of time spent on daily routine tasks such as insurance reimbursement submissions.

Ladies and gentlemen, if each of us in this audience tonight could influence just ONE young person to chose Pharmacy as a career, we could do much to sustain this as a viable profession.

So the objectives of this Board are clear – FUNDS, Fundraising, Unification, Numbers, Direction and Shadowing. Obviously, we will continue to monitor and lobby our representatives for legislation that is beneficial to our profession. As in the past, we will take positions that foster the growth and prosperity of Pharmacy in this state.

Through your continued support and the dedication and hard work of our Board of Trustees, we will continue to move Pharmacy forward in Maryland. We are looking for members who wish to become more involved with this organization. There are many jobs to be done and there are contributions *you* can make. We are proud of who we are and will continue to promote Pharmacy as an indispensable part of our health care system. Thank you for being here tonight and for your commitment to the Maryland Pharmacist's Association. You do make a difference! May God bless Maryland Pharmacy and may God Bless America.

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Director's Commentary

Over the loud objections of the pharmacy community, the Republican dominated House of Representatives passed H.R. 4954, the Administration's flawed Medicare prescription drug program. The pleadings of the pharmacy community did not fall on deaf ears. However, the vote with few exceptions, was straight down party lines. This is not the end of the story. The Graham bill (S. 2625) is the favored vehicle of the Democratic majority in the Senate, while a GOP alternative, similar to the House version, is also likely to be considered. Both rely heavily on PBMs to achieve savings and are not considered favorably by the pharmacy coalition.

The Senate is also considering an amendment codifying into statute the ability of states to extend Medicaid prices on drugs to low income seniors. This is what Maine did; PhRMA sued and the case is currently before the Supreme Court. This amendment would additionally allow states to use prior authorization for the drugs of those manufacturers who decline to participate in a rebate agreement.

Meanwhile, Kathleen Kennedy Townsend, Democratic candidate for Governor and Cass Taylor, Speaker of the Maryland House, have each separately announced support for prescription coverage for the uninsured by the State. The model that candidate Townsend used is HB6 from the 2001 legislative session except that her version has no income limits. HB6 uses the Medicaid fee plus \$1 and requires rebates from manufacturers. Not too bad right now, but no one knows where the Medicaid fee will be in a year or two. At present the Medicaid Department of the Department of Health and Mental Hygiene is in discussion with various representatives of



Howard Schiff
Executive Director

pharmacy to alter the regulations because of the budget deficit. For the first time in many years, DHMH is listening to people in the field to get an idea of cost-containment to avoid slashing pharmacy reimbursement from AWP-10% to AWP-13%.

What does all this mean to pharmacists working the “bench” in community, long term care and health systems? Sure, we all favor better health care including prescription coverage, particularly for our seniors. However, more prescriptions means more third parties, more technology from permit holders, more chance for error, more auxiliary personnel to train and probably more “burn out.” What can we do about it? Make your views known. MPhA is your representative for pharmacy as a profession in Maryland. If you have an opinion about our direction, let us know. Stay active and encourage your colleagues to be active. Not everyone can devote a great deal of time to a volunteer organization, but everyone has the time to say something about how they spend their working life.



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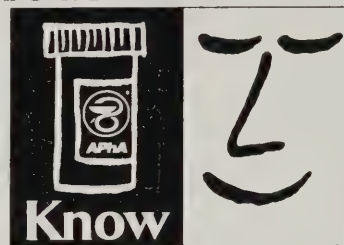
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The Anthrax Scare, OTCs, and Baltimore City Community Pharmacies

by Phillip Paul Weiner, Pharm.D.

An article appeared in The Sun on April 16, 2002 that, in essence, stated that monitoring sales of non-prescription drugs might help provide early detection of an anthrax attack. This was reported according to researchers at Carnegie Mellon University and had begun long before the September 11th attack and the anthrax scare that followed. When the anthrax scare was in full bloom, Pharmacy Times reported that legislation was being introduced by various state legislators to give public health authorities and state governors broad powers over the health care system in the event of a bioterrorist attack or naturally occurring epidemic. This legislation would extend to prescription as well as over the counter (OTC) preparations.

In my capacity as Consultant Pharmacist to the Baltimore City Health Department (BCHD), I am called on from time to time, to perform various functions for the Department. When anthrax spores were discovered in the U.S. Mail, Mayor Martin O'Malley and Commissioner of Health, Dr. Peter L. Beilenson, swiftly reacted in forming the Baltimore Bioterrorism Surveillance Network (BBSN).

One of the first acts by the Commissioner was to call a meeting of the leaders of the various health care elements involved in possible early detection of anthrax and other bioterrorism forms. The first request of pharmacy was to provide information from a few sentinel

pharmacies. I was asked to prepare a list of OTC items that could be used. My first thought was that this request was more difficult than believed, a thought that proved to be accurate. The next morning, I presented my supervisor, an Assistant Commissioner of Health, close to fifty pages of documentation that the task was much more involved than originally understood. There were hundreds of items, brand names, generic, store brand, crossover items that could be used for more than one purpose, and very specific items that could still be very difficult to assess.

After reviewing my document, I was requested to develop a tool to identify a small number of OTC items that could be monitored. Using the symptoms of anthrax infection as the marker, I placed the names of all of the OTC items that fit the symptoms. Next, I reduced the number of items so that only a few remained in order for the pharmacies to manage the task.

In the meantime, I obtained two lists of all of the pharmacies in the 212 zip codes. This list, unfortunately, proved to be somewhat difficult to manage as a number of the zip codes crossed borders with Baltimore County and one of the zip codes crosses Baltimore City, Baltimore County and a small piece of Anne Arundel County. There were a few chain pharmacy supervisors who were not positive to exactly which county the store belonged. In one case the difference was less than a stone's throw.

Dr. Beilenson had wanted a few sentinel pharmacies. A quick perusal of the list showed less than ½ dozen community pharmacies fit into the sentinel model, an insufficient number. In my opinion,

the most reasonable way to proceed was to visit the community pharmacies and to enjoin the chains to participate.

This article is based on the data that I collected my thoughts about the relevance of community pharmacy for this type of problem, and my thoughts on the heart beat of Baltimore City independent community pharmacy. Other than the data, which is accurate to the best of my knowledge, the views expressed here are mine alone as a pharmacist involved in community pharmacy for over 50 years ago, and must not be construed to be that of the City of Baltimore or the Baltimore City Health Department.

In general, I found that trying to obtain OTC data and translating that information into a useful database is difficult. Independent community pharmacies, with very few exceptions, do not sell a sufficient number of these items to be statistically significant. The chain pharmacies, as I discovered, each has their own sets of merchandise categories and special software programs would have to be written each time for new threat or set of symptoms. This would be costly. In addition, seasonal and intra store variations, and special sales further blurs the problem and therefore how to understand the data. To further cloud the problem, not all food stores, that sell a significant number of OTCs, have pharmacies and were therefore not included. The 7-11 type stores, the BJ's and Sam's Clubs, and the ma & pop groceries were also not included. All of these excluded, non pharmacy stores, sell a significant number of the items believed to be relevant to the anthrax problem. This dilutes the relevance of all of the pharmacy data in my opinion.

Taking another tact, I contacted McKesson Drug Company, the major wholesaler for the Baltimore Metropolitan area. One of the executives and I had a very pleasant and informative conversation about the reporting requests and problems. For a wide area, it could be helpful; for the City of Baltimore separately, McKesson would have the same problems as the chains. Pharmacies are set up by delivery route and most of the routes cross borders between Baltimore City and a surrounding county. Also, items containing a single ingredient can be found in multiple departments. As an example, acetaminophen and aspirin can both be found in 5 different department listings. Which one do we choose?

At the time of this data collection, around the middle of October 2001, there were 146 active pharmacy permits in Baltimore City: 39 independent, 28 hospital/clinic, and 79 chain. Of this number, 44 were either the hospital/clinic variety or were community pharmacies selling either no or very, very few OTCs. These were excluded from consideration. There are no pharmacies in zip code 21203 and only one in 21225. I discovered that one pharmacy had closed without advising the State Board of Pharmacy and one that was listed that had neither opened or had a sign up. I visited two pharmacies where the pharmacists were not present. One had a sign on the door stating that the pharmacist would return in 15 minutes, but did not return for 25 minutes after I arrived. The other was behind glass where a technician was filling prescriptions, but not dispensing them, until the pharmacist returned. He had gone to obtain medication for a waiting patient from another colleague.

The happiest visit was to a recently opened community pharmacy

owned by an African-American female who was trying to do it on her own. The store was bright, cheerfully lit, and reasonably inventoried. The saddest visit was with an older pharmacist whose store was a reflection of the neighborhood. Old, dirty, rundown, and locked up tight. We spoke for a few minutes and in passing, he mentioned that one of the chains had approached him about selling. I advised him that I thought it was time to do just that.

The overall goal of the BBSN was to provide the BCHD with an advanced network designed to identify signs of bioterrorism and other public health threats. The Network which met weekly during the initial period of the anthrax scare also collected data from other sources. Ultimately, the Network was working towards having the Emergency Departments reporting daily ER/ED visits that fit the syndromic patterns, daily ambulance runs from the Baltimore City Fire Department, daily reporting of deaths from the Medical Examiner's Office, cat and dog deaths from Animal Control, and daily reporting from sentinel private clinics operating in Baltimore City.

The several days I spent speaking with the pharmacists of Baltimore City proved again that we as public service professionals will do what is asked of us to help improve the health of the public we serve. We may not like or approve of the tasks, but we perform them with graciousness. I have always been proud to be a pharmacist. This project continued to validate my feelings.

The chain pharmacies reaction to the Commissioners Order was mixed. One chain had a software program written almost immediately

after the first meeting with the Commissioner. It contained about a dozen fast selling items contained in only 1 or 2 categories. Other chains, whose operation in Baltimore City numbered only a few stores stated that they would have to do it store by store. One chain declined to participate. A letter and four telephone calls to corporate headquarters allowed them to understand that the "request" was really an order. They too would accommodate the network.

In the final analysis, it is my opinion that the relevance of reporting OTC sales from pharmacies in Baltimore City by category and/or specific items would not be predictive of a bioterrorist attack due to anthrax. It will also be interesting to read the conclusions of the Carnegie Mellon study versus my opinion.

Listed below are the sources used to prepare the list of signs, symptoms, categories, and special items.

1. Consensus Statement, Anthrax as a Biological Weapon, JAMA, May 12, 1999 – Vol 281 No 18 PP 1735-1745
2. The Merck Manual 2000, Chapter 157 – Bacterial Diseases – Anthrax PP 1157-1158
3. The PDR For Non Prescription Drugs 2001, Section 3 – Product Category Index, 12 pertinent pages
4. McKesson Drug Company Generic Drug List – Effective Date 09/02/01 – 70 pertinent pages. Used with oral permission of Mr. Woods at the Landover Distribution Facility.

Signs/Symptoms**Categories of Pertinent Drugs****Special Items****Inhalation Anthrax***Primary*

Fever
Dyspnea
Cough
Headache
Vomiting
Chills
Weakness
Abdominal Pain
Chest Pain

Analgesics
Bronchodilators
Cough Medicines
Analgesics
Antiemetics
Analgesics
n/a
Analgesics
n/a

APAP, ASA, combinations
Primatine Inhaler, Bronkaid caps.
Robitussin,
Exceedrin, APAP, ASA
Emetrol
APAP, ASA, combinations

Antacids, H2 Blockers (not listed)

Secondary

Sudden Fever
Dyspnea

Diaphoresis
Shock

Analgesics
Bronchodilators
Analgesic Rubs
n/a
n/a

APAP, ASA, combinations
Primatine Inhaler, Bronkaid caps
Vicks VapoRub

Cutaneous Anthrax

Local edema
Pruritic macule or papule

n/a
Antihistamine Creams
Steroid creams

Benadryl, Caladryl,
hydrocortisone

Gastrointestinal Anthrax

Nausea
Vomiting

Malaise
Bloody Diarrhea

Acute Abdomen
Sepsis

Antiemetics
Antiemetics
Electrolyte replenishers
n/a
Antidiarrheals

Analgesics
n/a

Bonine, Dramamine, meclizine
Emetrol
Pedialyte, Infalyte

Donnagel, Imodium, Pepto-Bismol
Kaopectate
APAP, ASA, combinations



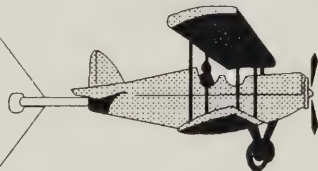
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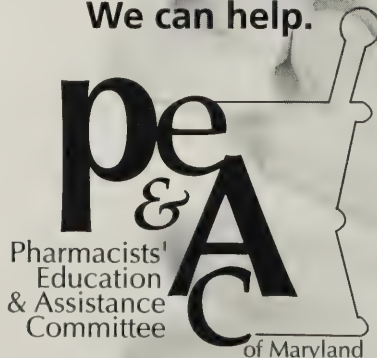
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Have Computers Caused an Epidemic of TMJ Syndrome?

By Robert Brundelre, D.D.S., R.Ph, P.A.

Temporomandibular Joint Syndrome or "TMJ? For short, arises from a dysfunction of the muscles, ligaments and/or bones that comprise the TM joint or jaw joint. This TM joint makes it possible to move the jaw in a wide range of motions including open and close, forward and backward and side to side. Although evidence is speculative or anecdotal at best, it is becoming more apparent that there is some connection between the increased number of TMJ cases and the increased use of computers.

TMJ Syndrome involves a complex array of signs and symptoms that may include but are not limited to:

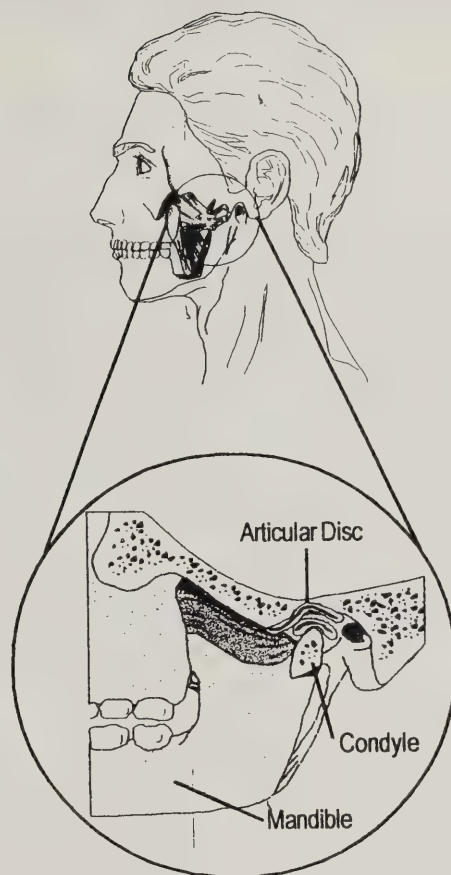
1. Headaches
2. Neck, shoulder and back aches
3. Popping, clicking and/or grinding in the jaw joints
4. Locking of the jaws (inability to open widely)
5. Sinus-like headaches
6. Pain behind the eyes
7. Ringing or buzzing in the ears
8. Dizziness and lightheadedness
9. Inconsistent tooth pain

A patient may experience several of these symptoms or maybe only a few depending on the severity of the dysfunction and the amount of damage to the TM joint.

Most of the problem is centered at the cartilage between the upper and lower jaw joints. Wear, stretching and damage to the cartilage (Meniscus-Articular Disc) due to trauma in the area, extreme stress or unconscious habits such as teeth clenching or grinding, prohibit the jaw joint from functioning properly. When this occurs, the jaw muscles will often go into spasm causing an arthritic-like pain in the jaw and if left to persist could cause permanent damage to the area.

However, TMJ may involve much more than the cartilage. All of the nerves, blood vessels, muscles and connective tissues of the head and neck unit may be contributing to the problem.

How does operating a computer cause the problem? From my observations and experience in treating TMJ disorder, the answer to the question is twofold.



Number one: The intense concentration that the computer requires precipitates a clenching response from the operator (i.e. gnashing of teeth). This puts pressure on the jaw cartilage and causes the facial muscles to go into spasm.

Number two: Positions of the head and neck structures of the operator precipitates spasm of all of the muscles in the entire area.

It is important to remember that in both of the above scenarios, the operator is almost always unaware of the negative habits until a problem like TMJ surfaces.

What is the choice of treatments? Foremost, consultation with a specialist trained in TMJ syndrome is essential. The choice of either a dentist, physician, osteopath or chiropractor would all be appropriate. There are a number of different therapies that these professionals may utilize. Possible treatments could include physical therapy, TMJ appliances, relations techniques, medications or a combination of all or some. A severe case may necessitate surgery, but surgery can be avoided if treatments are administered early.



During the Annual Convention Mayer Handelman explains the mission of the MPhA Foundation as he shows the artist renderings of the renovation plans for the Kelly Memorial Building and the B. Olive Cole Museum.

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Interactions . . .

On Behalf of Health Care in Maryland

The purpose of this column is to continually point out the many ways that the School of Pharmacy, MPhA and the pharmacists of Maryland interact to improve the health care of the citizens of Maryland. A few examples follow. There are many more!

Substance abuse education, research and treatment

Anthony Tommasello, Ph.D., associate professor and director of the School's Office of Substance Abuse Studies (OSAS), received the "Innovative Pharmacy Practice Award" at the 120th Annual Meeting of the Maryland Pharmacists Association (MPhA). The award was established in 1993 to recognize forward-thinking pharmacists who have expanded their practices into new areas. With the award, Tommasello was recognized for his many innovations as director of the OSAS, which he founded in 1986.

His current research projects include outreach to homeless substance abusers with HIV and mental illness, palliative care for end-of-life AIDS patients, tobacco use prevention and cessation, and policies for impaired health professionals. Under Tommasello's leadership, the OSAS develops and distributes information on substance abuse, sponsors several educational programs - including community service programs - that focus on prevention and treatment of substance abuse. The OSAS is also involved in research on substance abuse and publishes the quarterly newsletter PharmAlert.

"Dr. Tommasello has been committed to research and community service in the field of dependence and substance abuse since 1973," says Cynthia Boyle, PharmD, director of the School's Office of Continuation Studies and second vice president for MPhA. "He has created national models for education programs for the public, pharmacists, pharmacy students, and health and human service providers."

Under Tommasello's leadership, the Student Committee on Drug Abuse Education (SCODAE) enrolls student volunteers from across the campus who receive training and share insights with other students on the dangers of substance abuse, including alcohol abuse and binge drinking. These specially trained students then conduct drug education classes in middle schools throughout Maryland. A program under way for Tommasello and OSAS is "Project Mainstream," funded by the Association for Medical Education and Research in Substance Abuse (AMERSA), to enhance substance abuse training for all health care professions students at UMB, not just those specializing in substance abuse. Every summer, the



David A. Knapp, Ph.D., Dean
University of Maryland School of Pharmacy

University's Interprofessional Drug and Alcohol Program sends a group of students representing all seven schools to the University of Utah's "School on Alcoholism and Other Drug Dependencies." The OSAS organizes this effort and coordinates the activities of the students upon their return.

Health care professionals impaired by substance abuse and chemical dependency is also a long-standing concern of Tommasello and the OSAS. "The unidentified and impaired health professional is more of a public hazard than one who seeks help and gets into a treatment program," says Tommasello, whose office in 2001 helped co-sponsor a conference on practical, ethical and legal aspects of disclosing substance abuse and addiction in health care professionals.

"Uncounted professional lives have been rescued by his supportive services for pharmacists impaired by substance abuse and chemical dependence," adds Boyle.

Medication management agreements among prescribers, pharmacists and patients

MPhA members know full well the years of persistent effort necessary to pass a form of collaborative practice legislation in the General Assembly last spring. In May I was pleased to present the *Key to Pharmacy Hall* to George C. Voxakis, Chairman of the School of Pharmacy Board of Visitors, in recognition of his outstanding leadership in the multiyear battle to pass this legislation. Many School of Pharmacy faculty members and students actively participated in testifying and communicating with delegates and senators about this important topic. It is now up to the pharmacists of Maryland to demonstrate that the concept can work to the benefit of all concerned.

Bioterrorism preparedness

The Maryland Board of Pharmacy is taking the lead on this issue through a Task Force coordinated with efforts of the Department of Health and Mental Hygiene. Bruce Anderson, director of the Maryland Poison Center, and Ray Love, Vice Chair of the Department of Pharmacy Practice and Science, are playing major roles in the planning effort. The School will be offering special continuing education programs on emergency preparedness and bioterrorism in the near future.

Pharmacist workforce shortage issues

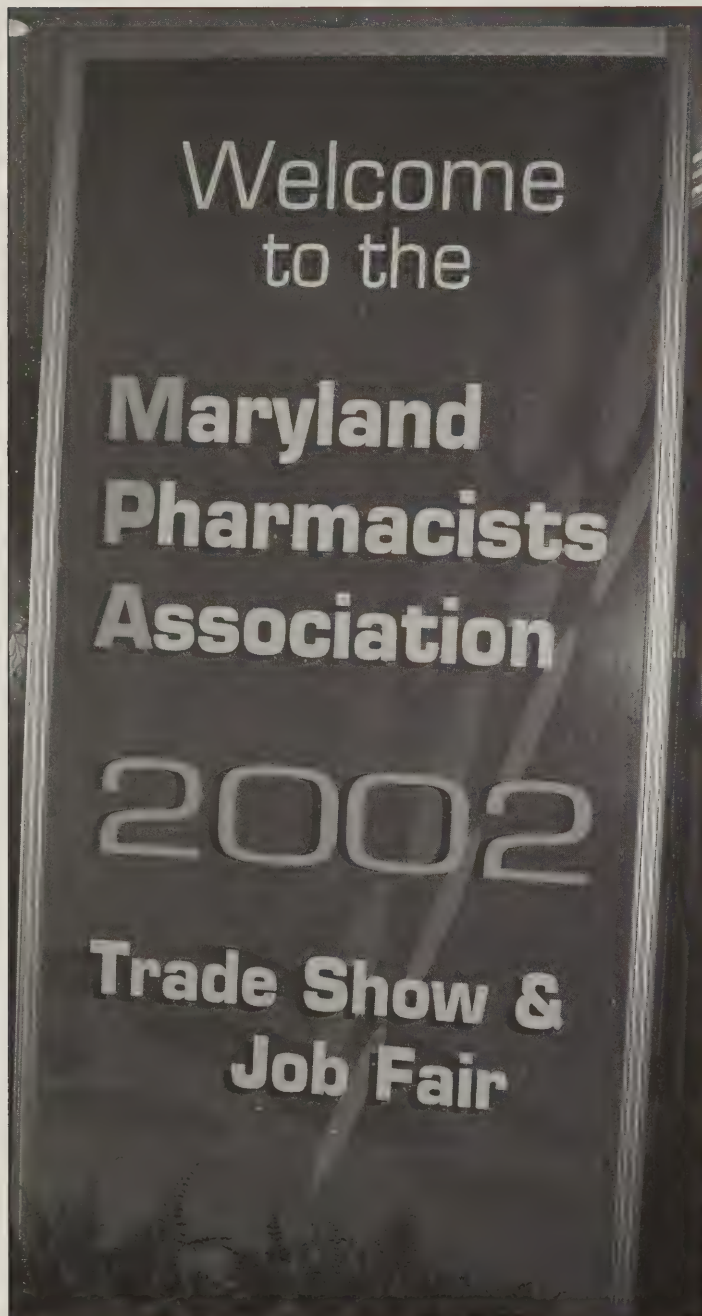
I serve on the Maryland Board of Pharmacist Task Force on the Shortage of Pharmacists, along with several MPhA members, including Executive Director Schiff. Associate Dean Bob Beardsley worked with the Task Force to create the web-based survey being used by the Board to assess the shortage situation.

The School is in the second year of its four-year effort to increase the enrollment of PharmD students by twenty percent. The applicant pool is holding strong, and the quality of entering students is high, despite the larger numbers. The enrollment increase places major demands on both space and faculty. In addition, rising tuition costs during the economic slowdown mean that we need more financial aid for students than ever. We are looking to pharmacists in the state to help future pharmacists in training either with direct financial assistance or through donations to our scholarship funds.

Experiential Learning Program for PharmD students

Enrolling twenty percent more students requires twenty percent more preceptor time! ELP director Richard Rumrill works hard to assure that all of our students have the quality and diversity of experience opportunities they need to take maximum advantage of their education. The contribution of preceptors cannot be overstated!

For his efforts in working with rural pharmacy, Director Rumrill has received the John Dennis Award from the Western Maryland Area Health Education Center. The award was presented during the Center's annual meeting in Cumberland in June.



120th Annual Convention



Trade Show

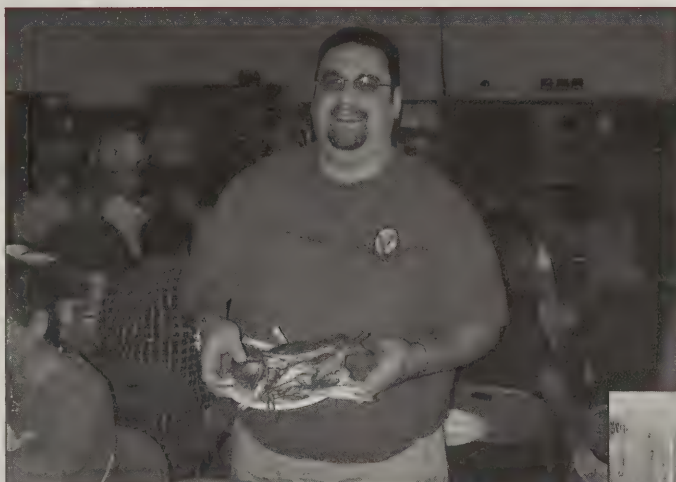


Volunteer Students visit the Trade Show



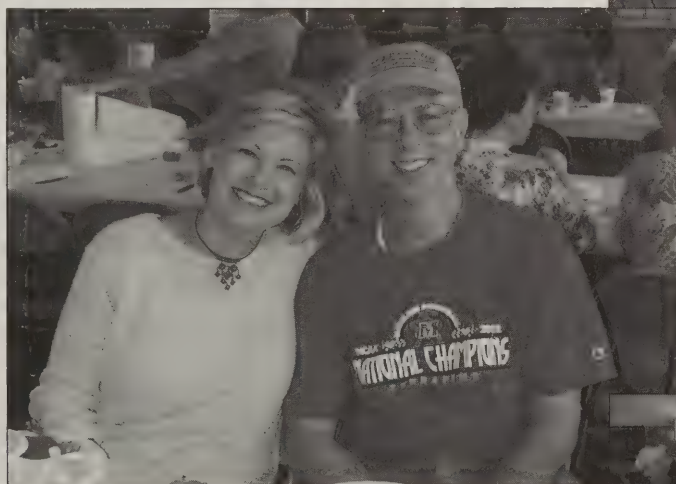
MPhA Foundation Booth

Ocean City, Maryland



Left: Hot Crabs!

Right: The Barbeque



Left: Dr. & Mrs. Bob Beardsley

Right: Crab Feast at the Berlin Fire
Department



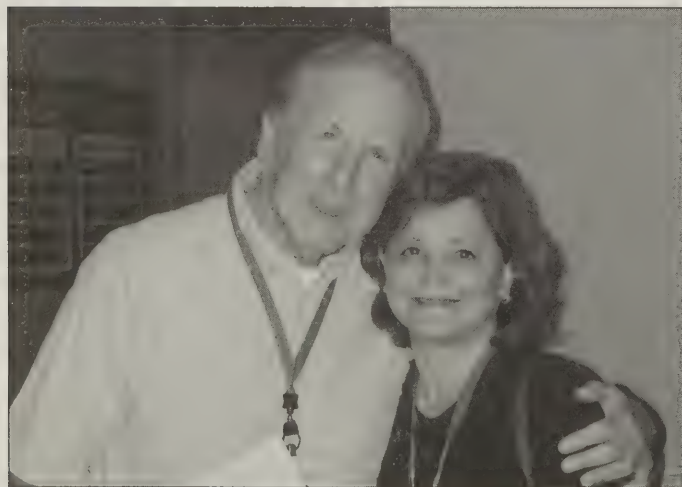
Annual Convention



Officers & Trustees



Classmates



Fred & Magaly



Student Volunteers

Improve Your Worklife

by Mark Jacobs, R.Ph., FASCP



What Would Einstein Do?

Taking an elementary approach to solving workplace issues

I once knew a dog named Einstein. He was really smart. Einstein was a companion dog for a friend of mine in Toastmasters International. Einstein would do just about anything you asked him to. He would sit and stand on command. He could get the mail, or a pen and paper. He could even retrieve a ringing phone. Forgot your slippers in the bedroom? - No problem, Einstein would go get them. One might say that he did everything right.

Albert Einstein (the person) was also very smart. Although he was Time Magazine's "Person of the 20th Century," he wasn't trained to do anything. In fact, he didn't even speak until age four or five. He actually strayed from the conventional way of thinking, by imagining his theory about time and space as many clocks traveling through space at different speeds. Once he had an idea about how his theory worked, he would spend days and even years on the grueling mathematics used to prove his theory. Sometimes it was so difficult, that he had to go to mathematics and physics professors for help.

I was wondering if we could learn something from the two Einsteins. If they were both asked to solve pharmacists' quality of work life issues, Einstein the dog would probably spend most of his time doing exactly what he was trained to do. He would probably do the same things day after day. He might even try doing them harder and faster. But in the end he wouldn't accomplish or discover anything new. He would always do what he's always done. We've all done this before.

Now let's consider how Albert Einstein might approach our work life problems. He would most likely:

1. Approach our problems with no preconceived notions.
2. Acknowledge that what we are currently doing is not working very well.
3. Not place the blame on someone else.
4. Realize that only he could solve the problem of feeling overeducated and underutilized.
5. Focus on the solution not the problem.

6. Imagine what the end result would be like, rather than the actual steps needed to get there.
7. Visualize and internalize that result so that he would become fixated on a solution to such a degree that he would lose sight of "all of those other things we do or did."
8. Realize that his real problem is no longer what it used to be. Instead it is filling in the necessary steps (the equation) to his solution.

Since Einstein didn't know everything, maybe his pharmacy technicians could help him with the difficult parts of the equation. Perhaps he would begin by:

- Reassigning some of his current duties to pharmacy technicians.
- Eliminating some courtesies such as calling doctors for refills—a value added service, but certainly not as valuable as face-to-face consultation with the patient.
- Consulting all patients on their drug therapy.
- Ask patients if it was working for them.
- Then determine if it was really working by using objective outcome parameters such as JNC-VI guidelines for hypertension or ADA guidelines for glycemic control.
- Recommend alternative medication therapy for the patient to introduce to their physician.
- Asking patients to follow-up with him at their next pharmacy visit.

Pharmacy employers may want to know how spending time doing these activities will help drive sales. You should consider the following, and come up with a few ideas of your own.

First, helping patients control their disease state by optimizing their drug therapy might lead to the addition of new drug therapy. At a minimum, you have the ability to impact the patient's compliance habits.

Secondly, by helping patients manage their prescription costs, you also may increase gross margin by switching to generic products.

(Cont'd. on page 24)

(Cont'd. from page. 23)

Thirdly, some Medicaid programs and HMO's reimburse pharmacists for these services.

Finally, satisfied patients may inform their doctor and friends about your expertise and helpfulness.

In my quest for reducing stress and improving professionalism in pharmacy, I often ask myself, "Am I truly overeducated and underutilized?" or, "Am I overutilized and undereducating patients?"

Why We Get so many E-Mails Forwarded to us

A man and his dog were walking along a road. The man was enjoying the scenery, when it suddenly occurred to him that he was dead. He remembered dying, and that the dog walking beside him had been dead for years. He wondered where the road was leading them.

After a while, they came to a high, white stone wall along one side of the road. It looked like fine marble. At the top of a long hill, it was broken by a tall arch that glowed in the sunlight. When he was standing before it, he saw a magnificent gate in the arch that looked like mother of pearl, and the street that led to the gate looked like pure gold.

He and the dog walked toward the gate, and as he got closer, he saw a man at a desk to one side. When he was close enough, he called out, "Excuse me, where are we?"

"This is Heaven, sir" the man answered.

Wow! "Would you happen to have some water?" the man asked.

"Of course, sir. Come right in, and I'll have some ice water brought right up." The man gestured, and the gate began to open.

"Can my friend," gesturing toward his dog, "come in, too?" the traveler asked.

"I'm sorry, sir, but we don't accept pets."

The man thought a moment and then turned back toward the road and continued the way he had been going with his dog.

After another long walk, and at the top of another long hill, he came to a dirt road which led through a farm gate that looked as if it had never been closed. There was no fence. As he approached the gate, he saw a man inside, leaning against a tree and reading a book.

"Excuse me!" He called to the reader. "Do you have any water?"

"Yeah, sure, there's a pump over there." The man pointed to a place that couldn't be seen from outside the gate. "Come on in."

"How about my friend here?" the traveler gestured to the dog.

"There should be a bowl by the pump." They went through the gate, and sure enough, there was an old-fashioned hand pump with a bowl beside it. The traveler filled the bowl and took a long drink himself, then he gave some to the dog.

When they were full, he and the dog walked back toward the man who was standing by the tree waiting for them.

"What do you call this place?" the traveler asked.

"This is Heaven," was the answer.

"Well, that's confusing," the traveler said. "The man down the road said that was Heaven, too."

"Oh, you mean the place with the gold street and pearly gates? Nope. That's Hell."

"Doesn't it make you mad for them to use your name like that?"

"No. I can see how you might think so, but we're just happy that they screen out the folks who'll leave their best friends behind."

Sometimes, we wonder why friends keep forwarding jokes to us without writing a word, maybe this could explain:

When you are very busy, but still want to keep in touch, guess what you do—you forward jokes.

When you have nothing to say, but still want to keep contact, you forward jokes.

When you have something to say, but don't know what, and don't know how, you forward jokes. And to let you know that you are still remembered, you are still important, you are still loved, you are still cared for, guess what you get? A forwarded joke.

So my friend, next time if you get a joke, don't think that you've been sent just another forwarded joke, but that you've been thought of today and your friend on the other end of your computer wanted to send you a smile. =)



HHS APPROVES EXPANDING PHARMACY BENEFITS TO MARYLAND SENIORS

Program to Provide Prescription Drug for 90,000 Maryland Residents

The program, created by the General Assembly in House Bill 6 in 2001 and then signed by the Governor, could not be enacted until the waiver was received from HHS.

The "Group I" quoted in the press release are those persons enrolled in the Maryland Pharmacy Assistance Program (MPAP). The program cost the State \$40 million last year. The waiver means that the federal government will pay \$20 million and the state saves the difference.

"Group II" enrollees may purchase prescriptions under the Medical Assistance Program at a price paid by the program minus the federally mandated manufacturers' rebate. Additionally, they will receive a 35 percent discount subsidized by Department of Health and Mental Hygiene. Pharmacies will be paid the Medical Assistance Program price plus a \$1 processing fee and will receive the 65 percent balance as copay.

HB 6 had other provisions, one of which was to establish a pharmaceutical care program and another to study the impact on "both independent and chain pharmacies."

Press Release from Health and Human Services on July 30, 2002

HHS Secretary Tommy G. Thompson today approved a Maryland program to provide Medicaid prescription drug benefits to low-income seniors. State officials estimate that as many as 90,000 Maryland residents may be aided by the new program.

"This creative program from Maryland helps those low-income seniors who are most in need of prescription drug coverage," Secretary Thompson said. "We will continue to support state efforts to expand drug coverage to seniors under this program even as we work to establish a drug benefit available to all Medicare beneficiaries."

Maryland is among the first states to receive federal funding to extend Medicaid prescription drug coverage to seniors using the principles of the new Pharmacy Plus initiative. HHS today also announced the approval of a similar program in South Carolina and previously approved similar programs in Michigan and Wisconsin.

Maryland's program targets seniors in two income groups -- those at or below 116 percent of the federal poverty level (FPL) in Group I and those whose incomes are at or below 175 percent of FPL in Group II. The FPL for 2002 is \$8,860 for an individual.

Participants would not otherwise be eligible for Medicaid and will receive only the drug benefit. Individuals in Group I (about 46,000 expected) are generally currently enrolled in a program run by the state. This includes non-elderly who are not disabled but may have a chronic illness such as diabetes or high blood pressure. All qualified Medicare beneficiaries (a program for very low-income Medicare enrollees) will also be eligible to enroll in Group I. Group I participants will receive a limited pharmacy benefit and related supplies. Under this amendment to the state's current 1115 waiver, both groups will receive all Medicaid drugs. Group I will have a \$5 copay for their prescriptions.

Individuals in Group II (about 44,000 expected) have slightly higher incomes and will receive Medicaid drugs at a 65 percent co-insurance. There will be no limitations on the number of refills for either group.

Since President Bush and Secretary Thompson announced the Pharmacy Plus initiative in January, many states are considering this type of Medicaid expansion to provide relief to low-income seniors in the face of increasing prescription drug costs.

Today's approvals come on the 37th anniversary of the day President Johnson signed the legislation that created the Medicare program to ensure seniors had adequate health coverage. By law, the Medicare program, which provides health coverage to about 40 million seniors and disabled Americans around the country, does not cover most prescription drugs.

Maryland's program and the Pharmacy Plus initiative are authorized through an expansion of Medicaid, a state and federal partnership that provides health benefits, including prescription drugs, to more than 40 million low-income Americans.

###

Do you remember?

Older than dirt...

My Dad was cleaning out my grandmother's house and he brought me an old Royal Crown Cola Bottle. In the bottle top was a stopper with a bunch of holes in it. I knew immediately what it was, but my daughter had no idea. She thought they had tried to make it a salt shaker or something. I knew it as the bottle that sat on the end of the ironing board to "sprinkle" clothes with because we didn't have steam irons.

Man...I am old!

How Many Do You Remember?

- Headlights Dimmer Switches on the floor
- Ignition Switches on the dashboard
- Heaters mounted on the inside of the fire wall
- Real Ice Boxes
- Pant Leg Clips for bicycles without chain guards
- Soldering Irons you heat on a gas burner
- Using Hand Signals for cars without turn signals

Older Than Dirt Quiz

Count all the ones that you remember. Do not count the ones you were told about.

- | | |
|--|--------------------------------|
| 1. Blackjack Chewing Gum | 13. Howdy Doody |
| 2. Wax Coke-shaped Bottles with Colored Sugar Water | 14. 45 rpm Records |
| 3. Candy Cigarettes | 15. S&H Green Stamps |
| 4. Soda-pop Machines that Dispensed Bottles | 16. Hi-Fi's |
| 5. Coffee Shops with Tableside Jukeboxes | 17. Metal Ice Trays with Lever |
| 6. Home Milk Delivery in Glass Bottles with Cardboard Stoppers | 18. Mimeograph Paper |
| 7. Party-lines | 19. Blue Flashbulbs |
| 8. Newsreels before the movie | 20. Packards |
| 9. P.F. Flyers | 21. Roller Skate Keys |
| 10. Butch Wax | 22. Cork Poppuns |
| 11. Telephone Numbers with a Word Prefix (Milton 6-6933) | 23. Drive-ins |
| 12. Pea Shooters | 24. Studebakers |
| | 25. Wash tub wringers |

The ratings

If you remembered 0-5 You are still young
If you remembered 6-10 You are getting older
If you remembered 11-15 Don't tell your age
If you remembered 16-25 You are older than dirt!

Pass this along...especially to all your really OLD friends.



Putting the Brakes on Abuse: How the Team Takes Action

"There is little research data on abuse and neglect in long-term care, but we know it happens," says Maura Conry, LCSW, PharmD, Psychiatric Clinical Coordinator at the Shawnee Mission Medical Center, Kansas City. However, there are tools and resources that team members can use to prevent abuse and quickly identify and act on instances that do occur.

Anatomy of Abuse

A broad definition of abuse, says Mario Cornacchione, DO, CMD, President of Pennsylvania-based Geriatric Research & Consulting Group, is a "willfully hurting or exploiting someone under your care." Of course, different state agencies and individual facilities may have their own definition. It is important to note that abuse does not just mean physical abuse. Abuse can be physical, emotional, mental, or sexual.

How much of a problem is abuse in long-term care facilities? National Ombudsman Reporting System data on total complaints brought to 52 state long-term care ombudsman program offices in 1998 showed that of the 15,501 complaints concerning nursing facilities, approximately 10% were related to abuse, gross neglect, and exploitation. However, it is difficult to track instances of abuse in nursing facilities. As Cornacchione notes, "There is no way of knowing whether states with higher reported abuse complaints actually have more abuse occurring, more aggressive abuse reporting systems, or some other outside influencing factors." Additionally, he observes, nursing facilities "have a high percentage of residents with cognitive impairment, and these individuals may not be able to report abuse or may not be believed if they do."

Facilities should not assume that abuse isn't a problem just because no or few instances of abuse are reported. Instead, they should foster an environment in which abuse is identified as well as prevented and encourage staff and patients alike to report suspected or actual instances of abuse. Toward this end, "it is important to ensure that every team member and employee know that there is zero tolerance for abuse of any kind," says Ruth Wilcox, RNC, NHA, BSN, workforce management manager at HCR ManorCare, Toledo, Ohio.

"Some individuals use language that is pretty ungracious," notes Wilcox, "but they don't see it as emotional abuse." It is important, she says, to have

intensive training programs that discuss what abuse is, who is most likely to abuse and be abused, and what situations are likely to cause someone to be abusive. This training should remind staff that yelling, name-calling, cursing, and threatening someone is just as much abuse as hitting or slapping someone. "A threatening or hostile look or shaking your fist at a frail person could be labeled as abusive," says Cornacchione. "When a resident turns on his call light and a staff person charges into the room in a threatening or hostile manner, this can be pretty humiliating or upsetting to a frail, sick person and could be labeled as abuse." It is important to emphasize that neglect—not feeding, bathing, or ambulating a patient appropriately—must also be taken very seriously. Although the regulations provide separate and different definitions for abuse and neglect, the latter is as serious as the former and must be addressed.

Watching for Abuse: Who, Why, and When

Any facility resident can be a victim of abuse. However, those at greatest risk include those who:*

- Have physical impairment that leads to dependence
- Have cognitive impairment
- Are frail
- Are incontinent
- Exhibit learned helplessness
- Are argumentative, assaultive, hostile, intrusive, passive, passive/aggressive, and/or manipulative
- Sexually act out
- Are depressed
- Have a history of any kind of multiple incidents
- Have impaired ability to communicate (e.g., mute, demented, hearing-impaired)
- Are verbally abusive
- Lack family and/or friends who visit
- Have language and/or cultural differences that staff don't fully comprehend

Don't expect all abused residents to report the problem promptly and readily. "Just like abused spouses or children," says Deborah Workman, executive director of Elder Abuse Prevention, Richmond, California, "abused elders often feel ashamed of and/or responsible for the abuse they incur. They also worry about retaliation if they report the abuse." At the same time, adds Conry, "nursing facilities have a high number of cognitively impaired residents who can't report instances of abuse in a way that is understood."

Staff or caregivers who are most likely to be abusive have one or more of the following situations or problems:*

- Stressful personal lives
- Mental illness
- Alcohol/drug abuse
- Chronic physical illness
- High levels of job burnout
- Excessive absenteeism/tardiness
- Numerous disciplinary actions
- Conflict with residents over food/hygiene
- Negative attitude towards elderly and disabled
- Lack of empathy
- Family problems/history of family violence
- Learned retaliation
- Violence as a way of life
- Financial problems
- Insubordination/power conflicts/rivalry
- Poor training
- Tendency to look to resident to fulfill their own needs
- Social isolation
- Low status
- Pay that is inconsistent with perceived worth of work

While most abuse in nursing facilities comes at the hands of staff and caregivers who have the most contact with the resident, staff at any level can be responsible for abuse. At the same time, abuse can also happen at the hands of visitors or other residents.

Abuse Prevention: Education Is the Key

As much as facilities and team leaders are committed to preventing abuse, there are barriers to identifying and stopping abuse. These include confusion on staff's part about what constitutes abuse. For example, says Conry, "isolation is a cruel form of abuse. Yet, staff may isolate difficult patients in their rooms or inadvertently prevent a hearing-impaired patient from communicating by not recognizing the

need for a hearing aid." Thorough and ongoing education and training are the best means to empower team members to identify and prevent abuse.

Beth Hudson Keller, MA, of the Philadelphia-based Center for Advocacy for the Rights and Interests of the Elderly (CARIE), suggests training programs that take a preventive approach. "We have staff take several steps back from caregiving to look at the whole picture of providing care. We look at issues such as challenging behaviors and how various events and situations make people feel and act," she adds. CARIE's education programs also talk about how the realities of today's healthcare system—staffing shortages, lack of supplies, ineffective or inadequate supervision, etc.—affect care and how these challenges, left unchecked, can lead to abuse and neglect.

Keller stresses that any training and education program about elder abuse should avoid a punitive approach. "You have to look at all of the elements that go into instances of abuse. You have to give staff an opportunity to talk about how difficult their jobs are and the stresses and difficulties they face," she offers.

Team leaders should be encouraged to participate in training programs, suggests Diane Menio, also of CARIE. "Initially, our training program targeted nursing assistants. But we learned quickly that we need to reach administrative, medical, nursing, and other staff and individuals," she says. "So much of this is tied into facility culture. You need buy-in from leadership, or staff will have a difficult time implementing what we teach them."

Training with Staying Power

"Consistent content has to be integrated into every kind of inservice and educational opportunity the facility offers," says Menio. "If a facility embraces this principle as part of its practices, training can be very meaningful."

Menio and Keller encourage the use of pre- and post-tests to help measure the impact of training programs. "These can be very revealing," Menio says. For example, she notes, "we've been surprised at how many staff see residents as being like children. So we emphasize in our program the importance of seeing residents as the individuals and unique human beings that they are. We remind them that many of our patients were once doctors, lawyers, teachers, war heroes, and community leaders."

"We encourage activities that will serve as reminders long after the training is over," Menio observes. These include posting photos of residents as young men and women or brief life stories above residents' beds. Holding a "Cultural Awareness Day" in the facility is another way of reminding staff about what they learned in training. Keller adds that some facilities have ongoing stress management seminars to address stress-related issues identified in training programs. Still others have problem-solving sessions, where team members meet to discuss a few different challenging residents each week.

Taking a Fresh Look

Don't make assumptions about what you think people know or should know, Menio cautions. "A lot of times it's a wake-up call for staff when you talk about psychological abuse and various types of neglect. They often don't realize that when you tell an incontinent resident you'll come back in five minutes to take them to the bathroom and you don't come back for an hour, this can be painful and humiliating for the resident," she offers. Discussing real-life situations and how they impact residents can help staff rethink how they act and talk on a daily basis.

*Adapted from "Preventing and Handling Elder Abuse & Neglect in Nursing Homes," a videotape program from Geriatric Video Productions, www.geriatricvideo.com

Reprinted with permission from LTC Exchange a quarterly newsletter published by Johnson & Johnson Long-Term Care Group

In Memoriam

Over the last year the Maryland Pharmacists Association lost three of its past presidents, Tony Padoussis, Nick Lykos and Elwin Alpern. All three had dedicated themselves to pharmacy and to the Association.

Tony was president in 1973. He had served as president of the Baltimore Metropolitan Pharmacists Association (BMPA) in 1970 and the Alumni Association in 1971-2 before his MPhA presidency and later became a member of the State Board of Pharmacy. Tony received the Bowl of Hygeia in 1975.

Nick was president in 1992 and had previously served for several years as treasurer. In 1996, Nick received the Bowl of Hygeia for his community service with his church, the Lyric Opera House and the Towson Chamber of Commerce. Nick was my colleague and friend for 45 years.

Elwin was president in 1988 after serving as president of BMPA. He was chairman of the Convention Committee for many years and was also chairman of the Travel Committee. Elwin was a personal friend, and along with the late Charley Spigelmire, was responsible for getting me involved in association activities.

We will miss Tony, Nick, & Elwin

Howard Schiff



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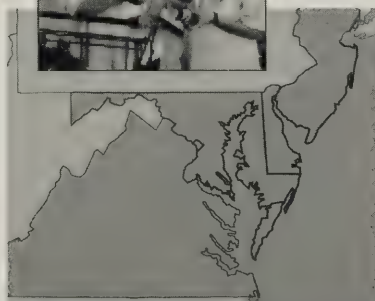
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AND THE LAW

By Kenneth R. Baker, B.S.Pharm., J.D.

This series, **Pharmacy and the Law**, is presented by Pharmacists Mutual Insurance Company and your State Pharmacy Association through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community.

TWO STATE SUPREME COURTS DECIDE, “WHAT IS THE PHARMACISTS DUTY?” ONE GETS IT WRONG

Howard Stark, R.Ph., FACA, was irritated. No lawyer would ever understand the source of Howard's irritation, but most pharmacists would. Howard's pharmacy had been sued even though he had done everything correctly and professionally for his patient, Mr. Kampe. That was not, however, why Howard was irritated. Howard's irritation was caused by the fact that he WON the lawsuit, or more specifically, how he won the suit.

In the case, Kampe v. Howard Stark Professional Pharmacy, Inc.¹, the patient alleged the pharmacy failed to “warn, counsel, evaluate, or verify the appropriateness of prescriptions, including controlled substances.”² The actual facts were that the pharmacist had warned, had counseled and had evaluated the prescriptions. These facts never came out, however, because the Court ruled that the pharmacy had only a “. . . limited duty to properly fill lawful prescriptions.”³ That is why Howard was irritated. “That Court says my only job is to

throw pills in a bottle! Pharmacists have higher standards than that. How dare they say that!”⁴

A few years later Missouri announced a new pharmacist standard, more closely agreeing with Howard. In 1999 the Missouri Court of Appeals rejected the Kampe Court's extreme “limited duty” theory saying:

Relegating a pharmacist to the role of order filler, as the Kampe court seemed to do, fails to appreciate the role recognized in [the pharmacy practice act and OBRA 90]. We reject the suggestion in Kampe that the only functions which a pharmacist must perform to fulfill his duty is to dispense drugs according to a physician's prescription.⁵

¹ Kampe v. Howard Stark Professional Pharmacy, Inc. 841 S.W.2d 223 (1992).

² Kampe, supra at 223.

³ Kampe, supra at 226.

⁴ Conversation between Ken Baker (author) and Howard Stark immediately after the decision was published, September 1992.

⁵ Horner v. Spalitto, 1 S. W.3d 519 (Mo. Ct App. Western Dist. 1999)

Now, in 2002, Howard may be irritated again. This time the Court is the Massachusetts Supreme Court. And, like the Kampe Court, Howard may feel the Court lacks respect for the professional abilities and duties of pharmacists. In *Cottam v. CVS Pharmacy*⁶ the court was faced with “the issue whether a pharmacy has a duty to warn its customers of the potential side effects of the prescription drugs it dispenses.”⁷

Specifically the case explained that the plaintiff (patient) brought a “negligence action against [CVS] pharmacy arising out of pharmacy’s alleged failure to warn patient about prescription antidepressant drug’s potential side effect of priapism, which, if not immediately treated, could cause permanent impotence.” After reviewing decisions from other courts and other states (but apparently not the state pharmacy practice act or ORBA 90 regulations), the Massachusetts Supreme Court held: “where the pharmacist has no specific knowledge of an increased danger to a particular customer, the pharmacist has no duty to warn that customer of potential side effects.”⁸

Unfortunately for CVS the court’s holding did not mean they won. To the contrary, the Court said that since CVS gave the patient a computer generated information leaflet, which the Court said a patient could mistake for a “comprehensive list of all known side effects”, then CVS legally volunteered to take on additional, non required duties and thus, the Court said “. . . it is appropriate to impose on the pharmacy a duty commensurate with what it appeared to have undertaken” (i.e. to warn of the side effect).

So what is the extent of the duty of a pharmacist in Massachusetts beyond that of, in Howard’s words, “throwing tablets in the bottle”? Can the answer in Massachusetts be that if pharmacists do nothing, then they have no other duties? Probably not, for while the Supreme Court may have a limited view of pharmacists, the Board of Pharmacy holds them to a higher standard. In Massachusetts, as in most states, pharmacists who fail to at least offer to counsel, fail to

perform prospective drug reviews and who act as if their only duty is to accurately fill prescriptions, may violate Board regulations and may be subject to disciplinary action.

Howard could also take heart in light of a decision at the same time from the Illinois Supreme Court. In *Happel v. Wal-Mart*⁹ the Court found pharmacists have a duty to warn. Quoting the Appellate decision, the Illinois Supreme Court held:

. . . [W]here defendant knew of Heidi’s allergies, where defendant knew that Toradol was contraindicated for a person with Heidi’s allergies, and where defendant knew that injury or death was substantially certain to result, defendant had an affirmative duty to disclose, either to Dr. Lorenc or to Heidi, the information that Heidi should not take Toradol. 316 Ill. App. 3d at 629.

Courts often do not understand pharmacy. The majority of recent cases have expanded pharmacists’ duties beyond that of merely correctly filling prescriptions. There have been, and will in the future be, Courts applying outdated standards to the profession. Pharmacists should not rely on these decisions to stop performing as trained, educated professional pharmacists. The true judge of the standards of practice of the profession of pharmacy is the practicing pharmacist.

© Kenneth R. Baker is Vice President, General Counsel at Pharmacists Mutual Insurance Companies.

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with the policies and procedures of their employers and insurance companies, and act accordingly.

⁶ *Cottam v. CVS Pharmacy*, 436 Mass. 316 (Mass. 2002).

⁷ *Cottam*, supra at 316.

⁸ *Cottam*, supra.

⁹ *Happel v. Wal-Mart*, ____ IL ____ (Ill. 2002).

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Continuing Education for Pharmacists

Volume XIX, No. 10

Patient Counseling: Glaucoma; Part 2: Treatment

**J. Richard Wuest, R.Ph.,
Pharm.D.**
Professor Emeritus
University of Cincinnati
Cincinnati, Ohio

and

Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology and
Toxicology
Ohio Northern University
Ada, Ohio

Goal. The goal of this lesson is to identify and discuss drugs used to treat glaucoma, and present points of information that can be used in counseling patients with this disease.

Objectives. At the conclusion of this lesson, successful participants should be able to:

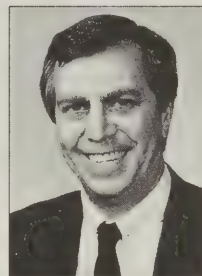
1. exhibit knowledge of the pharmacologic classification and therapeutic considerations for the drugs discussed;
2. select from a list, the mechanisms of action, benefits, and limitations of the drugs presented;
3. identify adverse effects and major toxicities associated with these drugs; and

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4. demonstrate an understanding on how to counsel patients on the drugs reviewed.

Glaucoma, as explained in Part 1 of this two-part series, is characterized by elevated intraocular pressure (IOP), which can lead to optic nerve damage and loss of vision. Left untreated, glaucoma may eventually lead to blindness.

Increased IOP can result primarily from either increased production of aqueous humor or decreased outflow. More than 40 types of glaucoma have been identified, but most cases fall into the following categories: primary open-angle, angle-closure, congenital, and secondary.

Primary open-angle glaucoma is by far the most common form. Medical treatment of open-angle glaucoma consists mainly of increasing the outflow of aqueous humor from the intraocular area or decreasing the formation of aqueous humor.

There are five major groups of topical drugs used to treat glaucoma: beta-adrenergic blockers (BAB); carbonic anhydrase inhibitors (CAI); cholinergic agents (miotics); prostaglandin analogs (PGA); and sympathomimetic agents (SYM).

The normal eye contains only a small amount of fluid (approximately 10 microliters). Most plastic

eye drop units deliver two to four times that much fluid per drop. Therefore, while eye drops must be administered carefully to maximize the dose of the drug placed into the cul-de-sac of the lower eyelid, the value of administering more than one drop at a time is highly questionable.

When multiple eye drops are prescribed for concurrent administration, the recommended interval between drops is five to 10 minutes to minimize flushing the first drop away, or overflow of the second drop when it is administered.

Suspension dosage forms dissipate from the cul-de-sac of the eye slower than solutions to provide a longer duration of activity. Ointments provide even longer contact between drug and ocular tissue. It has been reported that ointments slow the clearance rate to as little as 0.5 percent per minute. Gels provide drug release for hours. The Ocusert Ocular Therapeutic System provides constant, steady-state release of pilocarpine for longer than a week.

Several years ago, in an attempt to lessen confusion for patients needing to identify topical preparations, it was proposed that labeling and dropper caps be color-coded by therapeutic class. The first two to be so indicated were miotics and mydriatics (anticholinergics). Miotics, such as pilocarpine, are color-coded green (Green = Go for glaucoma). Mydriatics, such as atropine, are color-coded red (Red = Stop for glaucoma). Since then, blue and yellow have been selected for BAB, gray for NSAIDs, and brown or tan for anti-infectives.

Much has been written elsewhere that patients should hold a finger against the inner corner of

Table 1
Representative Ophthalmic Beta Adrenergic Blockers

Generic Name	Trade Name	Dosage Form
Betaxolol	Betoptic-S	suspension
Carteolol	Ocupress	solution
Levobetaxolol	Betaxon	suspension
Levobunolol	Betagan Liquifilm	solution
Metipranolol	OptiPranolol	solution
Timolol	Betimol, Timoptic	solution
Timolol	Timoptic-XE	gel forming solution

the eye at its juncture with the nose after instilling eye drops. This advice is given with the intent that it will reduce the amount of drug that gets absorbed into the body. While the authors do not challenge this advice, one wonders how significant the pharmacologic response would be from the small amount of drug in one drop.

Using timolol eye drops as an example, one drop of a 0.25 percent solution (2.5mg/mL) contains approximately 0.05mg of timolol. An unanswered question is whether this small amount would be able to elicit an action on any given receptor site after entry into the systemic circulation and dilution by approximately five liters of blood.

Given that the oral dosage of timolol is 10 or 20mg, what possible impact could less than 0.05mg of drug diluted and distributed throughout the blood have on the heart or lungs? Actually, this is a mute question for timolol eye drops because the manufacturers contraindicate its use in patients with sinus bradycardia, heart failure, bronchial asthma and COPD.

As will be discussed later, the manufacturers of cholinesterase inhibitors state that patients using these products should hold their lacrimal duct closed after instilling the drop, and this information should be passed on to patients. However, the point is that for other ophthalmic drops, each pharmacist must choose how he or she will practice pharmacy and what information to provide when counseling patients. This decision should be based on proven fact rather than "old wives' tales."

Beta-Adrenergic Blockers (BAB)

These agents act by blocking beta-adrenergic receptor sites in the eye. Their exact mechanism of action has not yet been determined, but the results are well documented. The BABs reduce both elevated and normal intraocular pressure (IOP) whether or not glaucoma is present. Since elevated IOP is a major risk factor for the progressive worsening of glaucoma, their therapeutic effectiveness is well established.

The BABs have displaced miotics as the agents of choice for treating most cases of glaucoma. This is due to their effectiveness, simple dosing regimen, and lower incidence of local adverse effects, especially less stinging on application with little effect on accommodation. More recently, the prostaglandin analogs are showing signs of replacing the BABs as agents of choice.

It is currently thought that BABs lower IOP by reducing the production of aqueous humor. There are reports that they increase the outflow of aqueous humor, but the significance of this action has not yet been determined.

Currently marketed BABs in ophthalmic dosage forms are betaxolol, carteolol, levobetaxolol, levobunolol, metipranolol and timolol. Table 1 lists commercially available BAB ophthalmic products.

As stated earlier, ophthalmic BABs are contraindicated in patients with certain pulmonary and/or heart disease, mainly because of the implication that topically applied drugs have the same systemic activity as orally administered

BABs. Carteolol, levobunolol, metipranolol and timolol are contraindicated in patients with asthma, COPD and heart disease such as sinus bradycardia and cardiac failure. Betaxolol and levobetaxolol are contraindicated in patients with asthma or COPD, but not heart disease.

Patient Counseling. The general patient counseling information for all eye drops is listed in Table 3. In addition, betaxolol and levobetaxolol products are suspensions rather than solutions and must be shaken well before use.

Timolol gel forming solution (Timoptic XE) has special patient instructions to invert the closed container and shake it once before each use to activate the product. It should be shaken only once. Since a gel is formed in the eye after administration, transient blurred vision occurs, lasting for 30 seconds to five minutes. This may impair the patient's ability to perform hazardous tasks such as operating machinery or driving a motor vehicle.

Carbonic Anhydrase Inhibitors (CAI)

Carbonic anhydrase is an enzyme distributed in numerous tissues throughout the body, including the eye. It reversibly catalyzes the reaction of water and carbon dioxide to form carbonic acid and sodium bicarbonate ions. Inhibition of carbonic anhydrase in the ciliary processes (linear folds that project from the ciliary body) decreases secretion of aqueous humor and lowers IOP. It is believed that CAIs, by slowing the formation of bicarbonate ion, reduce sodium and fluid transport out of the cells in the ciliary processes.

The CAI ophthalmic products currently available are brinzolamide (Azopt) suspension and dorzolamide (Trusopt) solution.

Patient Counseling. The CAIs are sulfonamide derivatives. Even though they are administered topically, their manufacturers warn that there is a possibility of cross-

allergy and sulfonamide-like adverse effects. They warn that patients should be advised that if serious or unusual ocular or systemic reactions or signs of allergy occur, they should discontinue the drug and consult their doctor.

Vision may be temporarily blurred following instillation of a CAI product. Patients should be careful operating machinery or driving motor vehicles. Azopt suspension should be shaken well before administration. Other patient counseling information for all eye drops is listed in Table 3.

Miotics

This drug class mimics the effect of acetylcholine on parasympathetic postganglionic nerve endings within the eye. The class is divided into direct-acting (cholinergic) agents and indirect-acting (anticholinesterase) agents. Direct-acting cholinergics (pilocarpine and carbachol) bind to acetylcholine receptor sites in the eye and stimulate parasympathetic fibers that innervate the ciliary muscle to cause pupillary constriction (miosis). Ciliary muscle fibers are also attached to the trabecular meshwork. Stimulating them promotes drainage of aqueous humor. Carbachol provides a more prolonged action than pilocarpine.

Cholinesterase inhibitors (demecarium [Humorsol] and echothiophate [Phospholine Iodide]) inhibit the enzymatic hydrolysis of acetylcholine and, thereby, prolong its endogenous activity to stimulate ciliary muscle contraction. These agents provide a much longer activity than the direct-acting cholinergic agents, possibly persisting as long as 10 days.

Patient Counseling. Miotics can cause difficulty in dark adaptation. Patients should be advised to exercise caution in night driving and other hazardous tasks in poor lighting.

The recommended administration technique for the gel form of pilocarpine (Pilopine HS) is to apply

a one-half inch ribbon in the lower conjunctival sac of the affected eye(s) once a day at bedtime.

Manufacturers of cholinesterase inhibitors contraindicate their use in women who are or become pregnant due to potential toxicity to the fetus. These manufacturers specifically state that patients should apply continuous gentle pressure on the lacrimal duct with the index finger for several seconds immediately following instillation of the drop; therefore, this concept is appropriate for these drugs.

Echothiophate requires reconstitution prior to dispensing using the diluent supplied by the manufacturer. There are indications that this product will be discontinued.

Prostaglandin Analogs (PGA)

Prostaglandin analogs are the most recent addition to therapeutics for glaucoma, and have become very popular. Latanoprost (Xalatan) was the first PGA released several years ago, followed by unoprostone (Rescula) in 2000, and bimatoprost (Lumigan) and travoprost (Travatan) in March 2001.

Xalatan has the longest track record and history of use and effectiveness. It is currently the most frequently prescribed glaucoma agent in the U.S. Claims are made that it is more effective than a BAB plus miotic (timolol + pilocarpine) and at least as effective as a BAB plus CAI (timolol + dorzolamide).

Xalatan, Rescula and Travatan are analogs of prostaglandin F₂ alpha. Lumigan is a prostamide

analog that mimics prostaglandin-like substances. The therapeutic activity of all four PGAs is to relieve IOP by opening channels that allow fluid between the iris and cornea to drain away.

Patient Counseling. The PGAs can cause changes to pigmented ocular tissue. The most frequently reported changes have been increased pigmentation of the iris, eyelids and eyelashes, and increased growth of eyelashes. The color change in the iris may be more noticeable in patients with more than one color in their eyes (such as green/brown or blue/brown). It may take months or years before these changes are noticeable, and they may be permanent.

If these agents are only applied to one eye, there is a possibility that the color change in the treated eye may be cosmetically different from the eye that is not treated. There may also be a disparity between eyelash length, thickness, color and number of hairs located near each eye.

General information for all eye drops is appropriate for the PGAs also.

The unopened bottle of Xalatan should be stored in the refrigerator. Once opened, it may be stored at room temperature for up to six weeks. Rescula and Travatan can be stored at temperatures between 36 - 77°F. Lumigan can be stored at room temperature.

Sympathomimetics (SYM)

Two classes of sympathomimetics

Table 2
Representative Sympathomimetic Agents

Generic Name	Trade Name	Dosage Form
Alpha- and Beta-adrenergics		
Dipivefrin	Propine	solution
Epinephryl borate	Epinal	solution
Epinephrine	Glaucon	solution
Alpha-2 Adrenergic Agonists		
Apraclonidine	Iopidine	solution
Brimonidine	Alphagan	solution

are available for treating glaucoma. The direct-acting (epinephrine and its prodrug, dipivefrin) and the alpha-2 adrenergic agonists (apraclonidine and brimonidine). These agents act by reducing aqueous humor production and increasing its outflow.

Epinephrine stimulates both alpha- and beta-adrenergic receptors. Dipivefrin is converted to epinephrine inside the eye by enzyme hydrolysis. Use of a prodrug is claimed to enhance absorption into ocular cells, decrease side effects, and enhance stability and comfort on application. Apraclonidine and brimonidine have more specific activity on the alpha-2 receptors in the eye.

The SYM agents do not produce the problems with accommodation caused by miotics, nor do they cause blurred vision or night blindness that occur in some patients using miotics. A list of representative sympathomimetic ophthalmic products appears in Table 2.

Patient Counseling. Most of the information listed for other ophthalmic products is applicable to the SYMs. The alpha-2 agonists contain an additional warning that they may cause fatigue and/or drowsiness in some patients. This could be questioned because so little drug reaches the systemic circulation. The warning is based on the drugs' chemical similarity to clonidine. Nonetheless, there is a warning in the "Information for Patients" section of their package inserts that patients using them who engage in hazardous activities should be warned of the potential for decreased mental alertness. Prudence dictates that this information be passed on to patients.

Combination Products

Therapy for glaucoma sometimes involves the use of products from more than one pharmacologic class. For convenience and increased compliance, fixed combinations are often advantageous for patients. Combinations currently on the

market include Cosopt (beta-adrenergic blocker with carbonic anhydrase inhibitor), and E-Pilo (epinephrine with pilocarpine).

At the time of preparing this lesson, a combination of Xalatan with timolol was under review by the FDA, and approval was imminent. This would be the first prostaglandin analog plus beta-adrenergic blocker available for treating patients who do not respond to either drug alone.

Administration Techniques

Manufacturers of most eye drops state that their product should not be administered with contact lenses in the eyes. The particles in suspensions may be absorbed into soft lenses, as can benzalkonium chloride and other preservatives in both multidose solutions and suspensions. The rule of thumb is to remove soft contact lenses prior to instilling eye drops. Generally with solutions or suspensions, lenses can be reinserted after 15 minutes. For ointments or gels which remain in the eye much longer, patients should discuss this with their physician.

Manufacturers state that if patients have ocular surgery or develop an ocular condition (e.g., trauma or infection), they should immediately seek their physician's advice concerning continued use of their multidose container. This is due to potential absorption of drug and preservatives contained in multidose dropper bottles through damaged tissue into the anterior parts of the eye, and possible contamination with pathogenic microorganisms.

For those patients who have trouble with flinching when administering an eye drop, a possible solution for this is to lie down, remove the dropper cap, hold the dropper bottle across the bridge of the nose with the tip just above the inside corner of the eye, and squeeze gently while aiming their eye away from the nose. This minimizes seeing the drop falling into the eye.

Another hint for avoiding the

Table 3 How to Administer Eye Drops

1. Wash hands thoroughly with soap and water and dry them.
2. For suspensions, shake the container well before use.
3. Make sure the solution is not discolored.
4. Remove the cap. Do not touch the dropper tip to any surface.
5. Tilt the head back slightly or lie down and look upward.
6. Pull the lower lid down and away from the eyeball to form a pocket.
7. Hold the dropper tip directly over the eye, but do not allow it to touch the eye or eyelid.
8. Place one drop in the pocket and continue to hold the eyelid for a moment while the medication runs in. To keep from blinking, look away from the dropper tip just before you release a drop.
9. Release eyelid and gently close eye for one or two minutes.
10. Do not squeeze the eye shut or rub it for a few minutes.
11. The drops may sting or burn, but the feeling should go away quickly. If irritation continues, tell your doctor.
12. Do not rinse the dropper. Replace the cap on the container.
13. Wash hands.

application of more than one drop is to keep the container in the refrigerator between dosing. Patients will be able to *feel* the first drop, which will be colder than tears and ocular tissue, making it less likely to inadvertently administer more than one drop.

If more than one medication is being applied concurrently, the rule of thumb is to wait five minutes between applications. If both an eye ointment and drop are being applied at the same time, the drop should be instilled first, and the ointment applied at least five minutes later.

Continuing Education Quiz

This month's questions are taken from the article on "Patient Counseling: Glaucoma; Part 2: Treatment." Circle your answers to the following questions and mail the entire page to Maryland Pharmacist CE, 650 W. Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members \$ 10.00). The completed quiz for this issue must be received by 10/15/04. A continuing education certificate for one and one-half contact hours (0.15 CEUs) will be mailed to you within six to eight weeks. Please type or print clearly. ACPE# 129-144-01-010-H01.

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1. All of the following are used to treat glaucoma EXCEPT:

- a. anticholinergics.
- b. beta-adrenergic blockers.
- c. carbonic anhydrase inhibitors.
- d. prostaglandin analogs.

2. Which of the following colors is used for the caps and labeling of eye drops to signify the product is a miotic to be used to treat glaucoma?

- a. Brown
- b. Green
- c. Orange
- d. Red

3. Which of the following products must be shaken well before administration because it is a suspension rather than a solution?

- a. Betagan
- b. Ocupress
- c. Betaxon
- d. OptiPranolol

4. Which of the following is contraindicated in patients with pulmonary or heart disease?

- a. Beta-adrenergic blockers
- b. Carbonic anhydrase inhibitors
- c. Direct-acting miotics
- d. Prostaglandin analogs

5. Which of the following decreases secretion of aqueous humor by slowing the formation of bicarbonate ion in the ciliary processes?

- a. Beta-adrenergic blockers
- b. Carbonic anhydrase inhibitors
- c. Direct-acting miotics
- d. Prostaglandin analogs

6. Which of the following mimics the effects of acetylcholine on parasympathetic postganglionic nerve endings in the eye?

- a. Beta-adrenergic blockers
- b. Carbonic anhydrase inhibitors
- c. Direct-acting miotics
- d. Prostaglandin analogs

7. Which of the following relieves intraocular pressure by opening channels that allow drainage of fluid between the iris and cornea?

- a. Beta-adrenergic blockers
- b. Carbonic anhydrase inhibitors
- c. Direct-acting miotics
- d. Prostaglandin analogs

8. Which of the following increases the pigmentation of the iris, eyelids and eyelashes, and increases the growth of eyelashes?

- a. Beta-adrenergic blockers
- b. Carbonic anhydrase inhibitors
- c. Direct-acting miotics
- d. Prostaglandin analogs

9. Which of the following is a prodrug of epinephrine?

- a. Apraclonidine
- b. Demecarium
- c. Dipivefrin
- d. Dorzolamide

10. Which of the following statements is appropriate to convey to patients applying two medications in their eyes?

- a. Apply both drops at the same time.
- b. Apply one drop in the morning and one at bedtime.
- c. Apply one in the right eye and one in the left.
- d. Apply one drop and wait five minutes before applying the second.

CORRECTION: The correct ACPE number for Patient Counseling: Management of Sore Throat which appeared in the Jan./Feb./Mar. 2002 issue of the *Maryland Pharmacist* is 129-144-01-011-H01.



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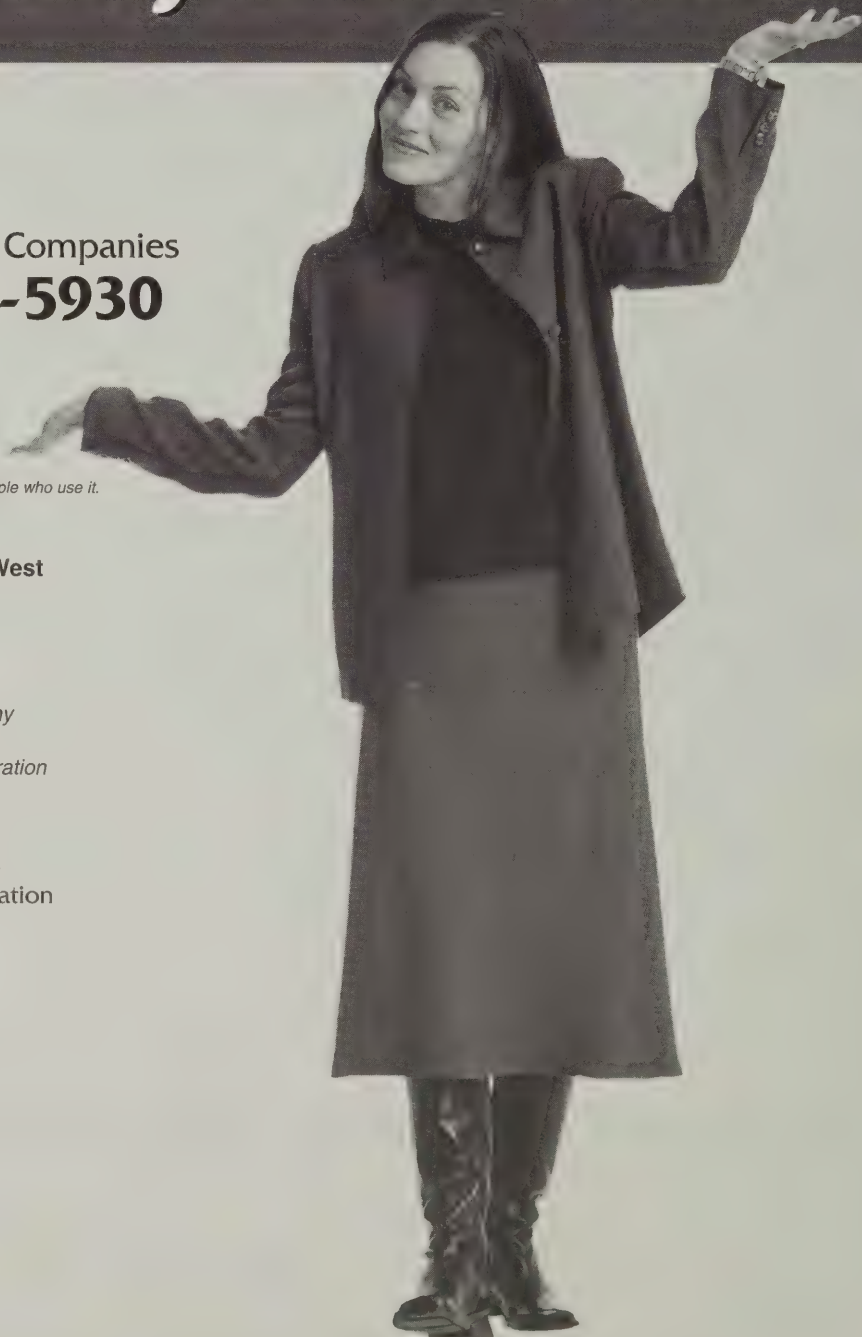
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The Official Publication of the Maryland Pharmacists Association

President's Commentary 5

MPhA Foundation 6

"Pledge Form"

Director's Commentary 7

"What's Going On?"

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Can Statins be Useful in Alzheimer's 15

Disease

Interactions... 17

The Future Pharmacy Workforce

Continuing Education 21

Patient Counseling: "Biological Terrorism"

Advertiser's Index

Giant	8
Mayer & Steinberg	19
McKesson	20
Medicine Shoppe	16
MPhA Foundation	6
PEAC	9
Pharmacists Mutual	4
PharmaSTAT	9
RPh on the go	8
Safeway	8
Walgreens	8
Wyeth	28

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Howard Schiff, Editor
Elsie Prince, Managing Editor



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PRESIDENT'S COMMENTARY

What if the Baltimore Ravens played a nationally televised football game at Ravens Stadium and no one showed up to watch? What if the Washington Redskins played the Dallas Cowboys on a bright fall Sunday afternoon at FedEx Field and no one showed up? What if the Maryland Pharmacists Association finally begins the remodeling of the Kelly Building and no one is supportive? Indeed, the first two scenarios would never happen. I am urging all members not to let the third scenario happen.

In 1953, the Kelly Memorial Building was dedicated as a permanent home for the Maryland Pharmacists Association. The building was named after Evander Frank Kelly, a former dean of the University of Maryland School of Pharmacy, a former Secretary of the American Pharmaceutical Association and the first to serve full time as the Secretary (now known as the Executive Director) of MPhA. This permanent home was the culmination of over seven year's worth of fundraising effort which yielded over \$100,000. This was a lot of money back in 1953 and it took dedication, commitment and hard work of its membership to achieve their goal of securing a permanent home for our association.



Paul R. Holly, P.D.
President

For nearly 50 years we have occupied this building without doing any major repairs or renovations. We now find ourselves in need of essential repairs and remodeling in order to be prepared to serve our association members in the future. A fund raising campaign was started four years ago. Phase One of the renovations included a new roof, new storm windows, exterior painting and brick washing. All of these were completed in 2001. While there is still not enough money raised to cover the remaining construction costs, the pledge commitments, donations, the sale of pill tiles, and other fund raising efforts have provided the minimum amount of funds needed to begin work on Phase Two of the remodeling. Phase Two began October 1, 2002, and includes remodeling the lower level which entails an improved display of the 1890's pharmacy and setting up a 1950's vintage pharmacy, complete with an operating soda fountain. Your Board of Trustees and Officers have wholeheartedly committed their human and fiscal resources to this undertaking.

Don't let the construction stop here. Have you made your contribution? *We need the help of all members in order to continue the renovations.* Phase Three plans include improving facilities to offer museum tours, displaying historical pharmacy artifacts; enhancing the current library; improving and expanding meeting rooms; providing educational programs for the public; initiating a scholarship program for state residents attending the University of Maryland School of Pharmacy; and providing resources for ongoing maintenance of the Kelly Building. Through your generosity we can meet our goals for improvement to our association's home and help ensure the future of the Maryland Pharmacists Association. What if the members of 1953 didn't make a contribution to invest in the future of our association? What if there wasn't an MPhA today? Who would be looking out for the interests and professional development needs of pharmacists in Maryland? What if you didn't make a contribution and our association wasn't there to support our members in the future?

The Maryland Pharmacists Association Foundation is a 501(c)3 nonprofit organization and contributions are tax deductible. **Don't delay. Make your contribution today.** Just as our members did almost 50 years ago, *make your commitment to the future of this association.*

To make a donation to the MPhA Foundation, contact the Executive Director of MPhA through our website at www.MPhA@erols.com/mpha or write to the Executive Director, Howard Schiff, at the Maryland Pharmacists Association, 650 W. Lombard Street, Baltimore, MD 21201 or contact Howard at 410-727-0746. For your convenience, a pledge form can be found in this publication and commitment forms and envelopes are also available if you wish to spread your donation across several years or have it deducted, with your authorization, periodically from a credit card account.

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Howard Schiff
Executive Director

What's Going On?

The most frequent question asked of me when I am approached by some members of the Association is, "What's going on?" I will attempt briefly to review what's happening and touch on some of the external "hot" issues affecting pharmacy where MPhA, as the voice of practicing pharmacists, should be heard.

In the Health Insurance Portability and Accountability Act of 1996 (HIPAA) is a section inappropriately named "administrative simplification." This section allows Health and Human Services (HHS) to set the rules for privacy, security, transactions and identifiers, all of which will change procedures in daily pharmacy activities. MPhA has had two educational programs on HIPAA and expects to have another at the Mid-Year meeting. We also have endorsed the manual produced by NACDS as a guide to compliance. Compliance is a must as of April 2003.

The state Medicaid department, seeking cost containment, called a meeting of interested pharmacy parties before the General Assembly met in 2002 and has continued to meet with us since that time. They have consulted us in good faith to avoid drastic cuts in pharmacy Medicaid reimbursements. Regulations will be ready shortly to avoid payment reductions from AWP-10%. Following are some of the changes:

- Eleven refills up to a 360-day supply will be allowed instead of two refills and a 100-day supply.
- The Department will institute a mandatory preferred drug list with prior authorization.
- Dispensing fees will be tiered (\$4.69 for generic and preferred drugs, \$3.69 for brand name drugs in the community; \$5.65 and \$4.65 respectively, in the nursing home).
- Co-pays will be tiered. (\$0 for generic and preferred drugs, \$2 for brand name drugs).
- Early refills will be more limited (80-90% usage instead of 75%).
- A 10 drug per month limit including refills will be instituted.

The Shortage of Pharmacists Task Force of DHMH has met monthly since December 2001. It has verified that there is a shortage, heavier in some geographical and practice areas than in others. Because of multiple state licensing, some pharmacists working more than one job or not working, and some leaving/coming into the state or work sites, exact numbers are difficult to quantify.

The Maryland Patient Safety Committee, working with the state's Office of Health Care Quality and the Maryland Health Care Commission, has been working on health system safety. Mandatory reporting for those medical errors resulting in death or serious harm will be in regulations effective in 2003. Voluntary, confidential reporting of less serious errors is expected to be made to a Patient Safety Center.

DHMH's Bioterrorism committee had its first training session in September and October. Several hundred pharmacists and techs have volunteered and 240 attended the first training sessions at the School of Pharmacy. It has been reported that pharmacy is far ahead of other health care professionals in planning and training phases.

The Maryland Pain Initiative was formed to advocate for better treatment of pain. The group has submitted names, including a pharmacist suggested by MPhA, to be on a Maryland State Pain Advisory Council. The Council is a result of a newly enacted state law.

Finally and most important, we have started on the remodeling of the lower level of the Kelly Building. The contractor is here and work is progressing. See President Paul Holly's article for further information.



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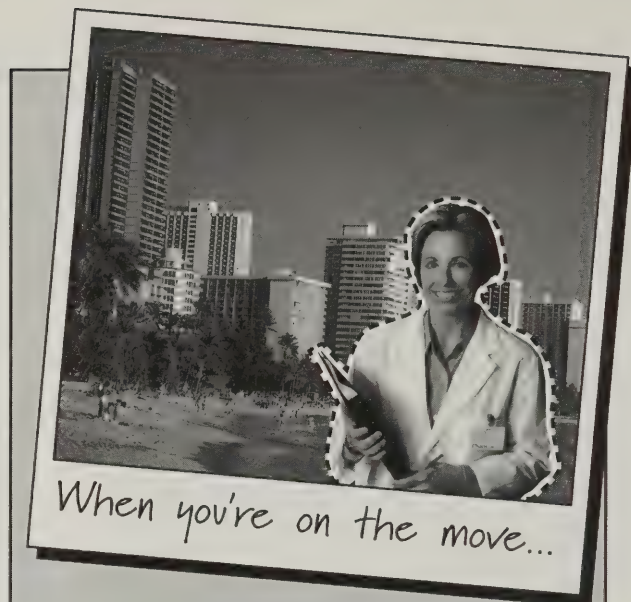
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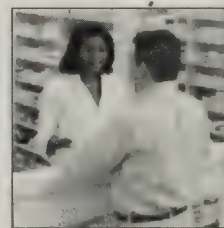
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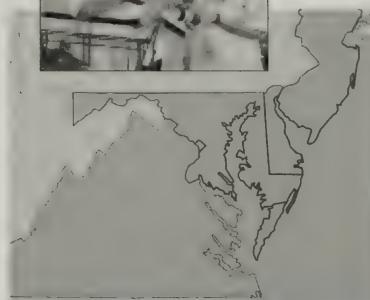
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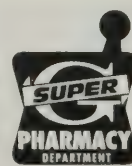
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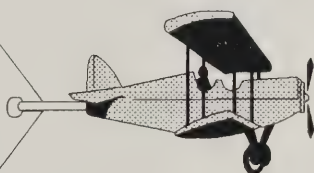
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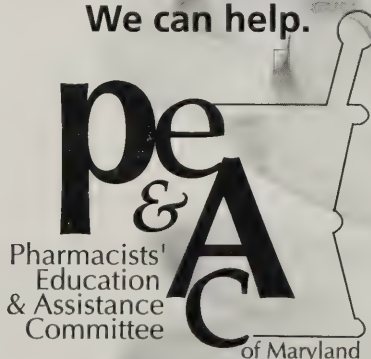
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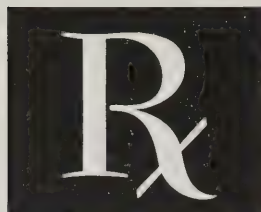


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Kenneth R. Baker, B.S.Pharm., J.D.

This series, **Pharmacy and the Law**, is presented by Pharmacists Mutual Insurance Company and your State Pharmacy Association through Pharmacy Marketing Group, Inc. a company dedicated to providing quality products and services to the pharmacy community.

PREVENTING THE SIMPLEST ERRORS

Every pharmacist's greatest nightmare is discovering that a patient has been harmed because of an error from his or her pharmacy that could have been prevented. We are all human and we can all make a mistake. Almost every error, when analyzed later, could have been discovered before it reached a patient, or could have been avoided in the first place.

Pharmacists Mutual's subsidiary, PMC Quality Commitment, Inc., develops quality programs for pharmacies. As part of these quality programs, the pharmacies track all errors and near misses through an Internet based system, which they can then use to further improve their quality and reduce errors. For the past several months we have been learning from these records. Some of the information is just what was expected, but some of it came as a surprise.

We had expected to find that most errors were either made at the time of computer entry or during the assembly or filling of the prescription. During one early review we discovered twice as many mistakes were made during computer entry than were made during the filling process. We had believed, and most pharmacists we interviewed believed, that mistakes in computer entry and in filling would have been about equal.

We had expected, from the Pharmacists Mutual Claims Study, to find that most errors, no matter in which process they occurred, would have been either that the prescription contained the wrong drug or wrong strength of drug. Over the years, each time we

reviewed the data from the Claims Study, we found that half of all claims were caused by wrong drug and twenty-five percent were wrong strength. What the PMC Quality Commitment, Inc. data shows, however, is that these two causes account for less than half of all prescription mistakes.

Our greatest surprise came during an early peer review of the data. We discovered that eight percent of all errors that reached the patient were filled exactly correctly. The information was put into the computer correctly. The correct drug was selected in the correct strength. The label was right and it was placed in the correct bottle. There should have been no problem, yet in eight percent of all errors reaching the patient, almost everything was wrong. After doing everything right, the prescription was placed into the wrong bag.

One reaction is that the patient should have caught the mistake and should not have taken the wrong drug. But, in several cases the patient did take the wrong prescription. Patients trust their pharmacists. Many patients would not consider that the bottle in the bag could be wrong. They simply open the bag, open the bottle and, knowing from the conversation with the physician how many to take, take the correct dose—of the wrong prescription.

Pharmacists have many ways to prevent mistakes in the computer entry process and in the filling process. How many pharmacists, however, have considered developing a method of making sure the correct bottle is in the correct bag? How many have a way to be

certain that the patient who is receiving the prescription is the right patient.

Consider a "Show & Tell" for each prescription delivered along with counseling technique using the Indian Health Service "Prime Questions"¹. Ask the person picking up the prescription to say to you certain information you can readily check from the receipt, such as the patient's name and phone number or address. Remove the prescription from the bag, read the patient's name as it appears on the label (not the receipt) and read the directions to the patient. Then open the bottle, show the tablet or capsule to the patient and ask, "What did your doctor tell you the medication is for?" Follow that with "How did your doctor tell you to take the medication?" The final question is "What did your doctor tell you to expect?" Now, fill in the blanks in the patient's knowledge as to the medication. Not only is this good counseling and good pharmaceutical care, but it is also a good way to be certain that the prescription is going to the correct patient. This is one way to prevent this "simplest" of all errors.

© Kenneth R. Baker is Vice President, General Counsel at Pharmacists Mutual Insurance Companies.

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with the policies and procedures of their employers and insurance companies, and act accordingly.

¹ The Indian Health Service developed "Prime Questions" counseling several years ago. Today, almost every school of pharmacy in the United States teaches some form of this counseling technique.



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Improve Your Work life

By Mark Jacobs, RPh, FASCP

Time Management in the Pharmacy

Efficient use of Time Will Leave More for Your Patients

Traditional time management techniques teach us to write a plan, list your goals and values, list each task that you want to accomplish, and then "work the plan." While these recommendations serve as useful tools for accomplishing your goals, they may fall short of your expectations as a pharmacist or pharmacy technician.

When the pharmacy opens at 8:00 a.m. or 9:00 a.m., all hell seems to break loose. If you can even remember what your goals were after 30 minutes into your work day, you might be lucky to



find time to implement them. That's because there are prescriptions to fill, check and dispense, insurance companies to deal with, illegible prescriptions, drug safety concerns, and telephones to deal with. And if that isn't enough, a drug rep is staring at you over the counter.

Pharmacists are like robots. We do what we were programmed to do. We are essentially, "task processors." If

we add up the number of decisions we make, we probably make over 1,000 of them daily including checking six to ten items on each prescription for accuracy and safety. One would only need to check 100 prescriptions to reach this limit. Then add on the phone calls and questions you respond to. The hectic nature of our work almost prohibits, at times, our ability to help patients understand and maximize the benefits of their drug therapy.

I've been noticing lately that doctors in my area have become fed up with their own hectic work lives, and they're starting to do something about it. Just the other day, I contacted a doctor's office for authorization on a prescription (something we rarely do). It was 2:30 p.m.—well before the typical 5:00 p.m. closing time. When I spoke with the receptionist, she informed me, "Dr. Jones is done taking calls for the day." "You mean that he's still there, but he's not taking any more calls?" I asked. "Yes," she responded, "you can call back tomorrow."

"Wow," I thought to myself. This doctor realized he was "maxed out" for the day. He was at "full capacity." No more...done! I joked with the pharmacy technicians I was with about the situation. What if we were to set a limit on our

workload like that? Can you imagine the look on our patients' faces if we told them that they could leave their prescription, but that they wouldn't be able to pick it up until tomorrow? [Stay tuned, because I'll be covering this topic in a future article this year.]

Now one might argue that pharmacy is a little different than a doctor's office, in that we provide an on-demand service, and they see patients by appointment. But the fact is, that doctor prevented us from providing *our* on-demand service even though it didn't require him to make an appointment with the patient. In one way, it didn't seem fair that he could do that but we couldn't. In another way, it seemed ingenious.

What can we do that will allow us to spend more time with our patients?

I offer you the following suggestions to consider. I would ask that you consider each one for its merits and disadvantages. Ideas for changing your pharmacy worklife have benefits and side effects just like a drug. If you use one, your goal is to maximize the benefits, and minimize the side effects.

1) Make full use of pharmacy technicians. *Do not* answer the phone unless it's a doctor's line.

I can't think of a single professional (lawyer, dentist, chiropractor, doctor, or even nurse) that answers his or her own phone.

2) Respond to questions on the phone through your pharmacy technician whenever possible.

Teach them to gather the right information for you to make an informed decision. This is no different than a doctor responding through the nurse.

A doctor once proudly informed me, "Patients have to get through both a receptionist and my nurse before they have a chance to talk to me directly. We solve their problems, but I don't need to talk with each and every one of them."

3) If the patient insists on speaking with a pharmacist, explain that the pharmacist is busy with a patient right now.

Have the technician take a name and phone number, and also document whatever the patient will tell you about their concern so that pharmacist can research the problem before they call you back.

4) Find out when and where would be the best time to call the patient back. This conditions patients to realize that you are a busy health care professional and that you may not be as "on-demand" as you used to be. If they really need help right now, they might reconsider asking their question via the pharmacy technician.

5) Gracefully exit the conversation after two minutes by explaining to the patient that you have time for one more question. They'll either ask it or thank you for your time.

6) Have the technician take down all information for prescription transfers, bring it up on the computer screen, and pull the original copy, before handing the phone to the pharmacist.

These and other strategies will help you gain some control over your work day. Make a commitment to start making small changes in your work environment every day. Talk with your staff about changing the way you currently do things.

Remember what Albert Einstein said, "*We cannot solve the problems of today with the same thinking that got us here.*"

Materials for this article was drawn from Mark Jacobs' 101 Ways to Improve Your Pharmacy Work Life, published by the American Pharmaceutical Association. To purchase this book, call 800-878-0729. Mark Jacobs is a pharmacist at Shopko Pharmacy in Beloit and served PSW for two years as an At-Large Director.

Can Statins be Useful in Alzheimer's Disease?

Kimberly A. Fisher, Pharm.D. Candidate
University of Maryland

Over the past several months, various media reports have been exploding with the news of a potential life-altering breakthrough in the prevention of Alzheimer's disease (AD). Recent epidemiologic studies have shown a correlation between the use of cholesterol-lowering statins, otherwise known as 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitors, and Alzheimer's disease. Evidence has suggested that high cholesterol is a risk factor for AD; nonetheless, is it safe to assume that reducing cholesterol levels with statins are a cure for Alzheimer's disease?¹

Before we dive into the realm of statin therapy, let's revisit Alzheimer's disease. Alzheimer's disease is categorized as a progressive, degenerative condition that breeds decline in cognitive functions such as memory, language, spatial ability, and self-awareness accompanied with noticeable behavioral changes. It is the most common cause of dementia found in the elderly population.^{1,2} Symptoms of Alzheimer's disease in its latter stages are devastating to family members since these patients become fully dependent on others to thrive. They include trouble in swallowing, walking, controlling bladder and bowel functions, maintaining mobility and eventually a change in personality. The typical findings in an Alzheimer's disease patient include neuronal plaque formation, neurofibrillary tangles, and amyloid deposition throughout the cerebral cortex and hippocampal regions of the brain. Without signs of neurofibrillary tangles and neuritic plaques anatomically, AD does not occur.^{2,3}

Several possible mechanisms have been implicated in the cause and progression of Alzheimer's disease. The amyloid hypothesis depicts one such theory behind the progression of this chronic condition and is thought to be the major mechanism behind statin therapy becoming a potential treatment. One such abnormal finding in the brain of an Alzheimer's patient begins with the amyloid precursor protein (APP) breakdown pathway. Normally, this nerve cell protective protein is broken down upon intracellular transport into several peptides. Once this breakdown occurs, all metabolites are cleared from the extracellular space. The A β -amyloid peptide, the minor by-product of this protein breakdown, has been shown to be increased in AD patients, and its clearance is not as complete as it would be in normal tissues. Due to the increase in the A β -amyloid peptide, amyloid fibrils start to deposit, which are now thought to be the precursors that trigger the formation of neuritic plaques. Deposits of this peptide lead to overall neurodegeneration, thus causing AD.¹

Statins, or HMG CoA reductase inhibitors, have shown some evidence in decreasing the production of A β -amyloid peptide in animals. Animal studies have revealed that cholesterol-rich diets tend to accumulate A β -amyloid peptide in the brain.⁵ These drugs efficiently cross the blood brain barrier, thereby reducing the de novo synthesis of cholesterol. Since cholesterol would be lowered throughout the body, the thinking is that this deleterious minor metabolite would be diminished, thus reducing these precursors responsible for the creation of plaques found in AD patients.^{1,4}

In an article published in the International Journal of Neuropsychopharmacology, the effects of lovastatin and its active metabolite, lovastatin acid, were tested on several human subjects. These subjects had prior elevated LDL cholesterol and were given varying strengths of the medication. The concentrations of beta-amyloid in their brains were then measured before and three months after the study began. The study clearly showed a dose-dependent decrease in the levels of beta-amyloid peptide compared to placebo.⁶ A second similar but more specific study conducted by Simons et al focused on forty-four Alzheimer disease patients with normal cholesterol levels. These participants were randomized to either receive simvastatin at doses of up to 80mg per day or placebo for a total of twenty-six weeks. Overall, the results obtained in the simvastatin group showed that in the mild Alzheimer disease patients, the amyloid beta levels in the brain were significantly decreased. On the other hand, in the more severe cases of AD patients, these same changes were not observed.⁷ While these outcomes are fascinating, even more questions of their effectiveness have arisen. How does the stage of the disease and the levels of cholesterol prior to treatment correlate with the effectiveness of these medications? These studies illustrate the many variables that play an important role in whether or not statins have an effect on the pathogenesis of AD.

As to date, there are few options in the fight against Alzheimer's prevention and treatment. Those medications currently available and used today are certainly not a cure but instead are an attempt to slow the progression of the disease's course. For example, acetyl cholinesterase inhibitors only cause a temporary improvement in functional status and a delay in symptomatic decline for the AD patient with mild to moderate disease.² Although this newfound information is a promising step in the right direction, additional lengthy, randomized, double-blinded controlled human trials must be performed to determine the clinical significance, if any, that statins may have on AD. In the future, statins may play an important role in Alzheimer's disease; however, it is premature to conclude them as definitive treatments.¹

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Interactions:

The Future Pharmacy Workforce

The Pharmacy Manpower Project Inc., a consortium of national pharmacy organizations and the Federal Health Resources and Services Administration, has recently released the report of a conference that came to a startling conclusion. In just 20 years the United States will face an unmet need of more than 150,000 pharmacists! That's a massive number, considering that the current number of practicing pharmacists in the country is just a bit over 200,000.

We are all aware of the current shortage of pharmacists. Who hasn't heard of the rapidly rising starting salaries, the lucrative sign-on bonuses, the special packages for practice in less attractive locations? We know that the number of prescriptions written continues to increase, driven by direct-to-consumer advertising and third party co-payments for most patients that are low enough not to deter obtaining prescriptions of marginal value.

But won't automation and the increasing use of technicians soon slow down the demand for pharmacists? What about the dozen or so new schools of pharmacy that have opened and the increases in enrollment at existing schools that have pushed up the number of pharmacists in training? And what about the data from NACDS that show the rate of prescription increases to be slowing? Isn't it possible that we will be faced with a glut of pharmacists in 20 years?

These were some of the questions considered by the national conference that was convened by the Pharmacy Manpower Project a few months ago. I was given the challenge of organizing and moderating the conference, but there was a very significantly different question that was also asked of conference participants. Given the dramatic difference in the age make-up of the U.S. population in 20 years, what will be the projected *need* for pharmacists to take care of the population's drug use issues? In other words, the conference was not only interested in the question of demand, the number of jobs for pharmacists, but also the level of health care need as measured by the projected use of both drugs and biotechnology products by patients in the year 2020.

The conclusions were stunning. The participants defined two major functions for pharmacists. The first was fulfilling the billions of prescription drug orders for both outpatients and institutionalized patients. Today these numbers are difficult to comprehend in the aggregate: about 3 billion outpatient prescriptions per year in the United States and almost 2 billion drug orders dispensed for inpatients last year. Compounding these numbers by only a few percentage points over 20 years results in some pretty large numbers! However, the conference participants concluded that advances in pharmacy automation, the use of computers and the use of pharmacy technicians, could increase the efficiency of order fulfillment by a factor of five. However, even accounting for this great increase in efficiency, the conference concluded that about 100,000 pharmacists would be needed to fulfill the oversight and supervisory functions required by the year 2020. Thus, there is little danger that pharmacists will not be able to find rewarding employment performing these functions over the next generation.

It is the second major function of pharmacists that raises concern, and that is the patient care function. Pharmacists have always helped patients and prescribers manage medications more effectively. The need for these pharmaceutical care functions will grow dramatically as the population ages. Despite much rhetoric to the contrary, the recent growth in prescription drug utilization has had *little* to do with the aging of the population. Although persons over the age of 60 are known to use about three times as many prescription drugs as those under 60, the baby boom generation has not yet reached that magic age! The first year that baby boomers appeared was in 1946, and they will not reach age 60 for another four years. Then, beginning in 2006 the nation will see the largest increase in the elderly population in history. This is not idle speculation; these folks are with us today. They represent the *demographic imperative* that will rule the



David A. Knapp, Ph.D., Dean
University of Maryland School of Pharmacy

healthcare industry for the next 25 years.

Unfortunately, the patient care functions of the pharmacist that the conference labeled as so important for the year 2020 are often unmet today. While the country is obsessed with expenditures for prescription drugs that now exceed \$150 billion dollars annually, it has largely ignored research demonstrating that we spend even more money cleaning up after the consequences of medication misadventures.

As we move inexorably towards the year 2020 and the inevitable overwhelming need for our patient care services, as pharmacists we must devise a way to be paid for these services so that the need will be converted into demand. This is a major challenge for both the profession and pharmaceutical education for the years to come.

**Current Use and Projected Need for Pharmacists in the United States
(Full Time Equivalents)**

	Current use of pharmacists 2001	Projected need for pharmacists 2020*
Order fulfillment	136,400	100,000
Primary services	30,000	165,000
Secondary/tertiary services	18,000	130,000
Indirect/Other services	12,300	22,000
Total	196,700	417,000
Total estimated supply		260,000
Shortfall		157,000

* These figures are estimates of the need for pharmacists in 2020 and not forecasts of market demand or jobs for pharmacists.

Source: Pharmacy Manpower Project report, "Professionally Determined Need for Pharmacy Services in 2020."



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Continuing Education for Pharmacists

Volume XX, No. 1

Patient Counseling: Biological Terrorism

**J. Richard Wuest, R.Ph.,
Pharm.D.**
Professor Emeritus
University of Cincinnati
Cincinnati, Ohio

and

Thomas A. Gossel, R.Ph., Ph.D.
Professor of Pharmacology and
Toxicology
Ohio Northern University
Ada, Ohio

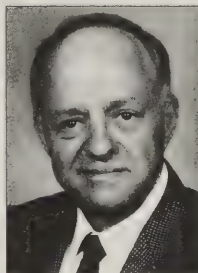
Goals. The goals of this lesson are to review information on anthrax, furnish information on what the government plans to do in case of attacks of bioterrorism, explain methods for protection against these attacks and provide information that can be used when counseling patients on the drugs of choice for treating anthrax infections.

Objectives. At the conclusion of this lesson, successful participants should be able to:

1. exhibit knowledge of symptoms of anthrax infection, its prevention and its treatment;
2. recognize government plans for responding to an attack of bioterrorism; and
3. demonstrate knowledge on information to use when counseling

*This lesson is provided by an
educational grant from*

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patients on drugs used to prevent and treat anthrax infections.

The discovery that the potentially deadly pathogen *Bacillus anthracis* (anthrax) was sent via contaminated letters through the U.S. Postal Service in early October 2001, caused a wave of fear in many Americans. This followed the terrorist attacks on the World Trade Center in New York City and the Pentagon in Washington D.C. three weeks earlier.

Experts have spoken and written about the possibility of bioterrorism for years, but these incidents raised the level of attention in this country. Early on, opinions expressed through the news media (and rank and file Americans) connected the anthrax-contaminated letters to the hijacked airline terrorist attacks. However, at the time of preparation of this lesson, proof of any connection had not been uncovered.

The CDC defines a *confirmed* case of anthrax infection as one that is compatible with the clinical signs and symptoms of the disease, and by laboratory tests showing the presence of *B. anthracis*. A *suspected* case is one that is clinically compatible with no supportive laboratory tests, or a clinically compatible case of anthrax epidemiologically linked to a confirmed environmental exposure, but without corroborative

laboratory evidence of the bacteria.

By November 2001, the Centers for Disease Control and Prevention (CDC) determined that there had been 17 confirmed and five suspected human cases of either cutaneous or inhalation forms of anthrax infection during this episode. These occurred in Florida, New Jersey, New York and Washington, D.C.

Of the confirmed cases, seven were cutaneous and 10 were inhalation infections. In the suspected category, all five were cutaneous infections. At this point, there have been only four deaths associated with inhalation anthrax from contaminated mail. Another anthrax-related death occurred in Connecticut in November 2001, but there was no linkage of that victim to the earlier mail-related deaths.

For the last half of the 1900s (record-keeping began in 1955), CDC received only 236 case reports of anthrax infection, mostly cutaneous. The last case of inhalation anthrax in the U.S. before 2001 was in 1976 in California. It involved a craftsman working with imported yarn from which *B. anthracis* was isolated. The last case of cutaneous anthrax infection (non-fatal) before 2001 was reported in North Dakota, in 2000. According to CDC, this was the only case seen since 1992.

Mailed letters containing anthrax spores were addressed to several individuals in the government in Washington, D.C. and a tabloid publisher in West Palm Beach, Florida. Postal workers at several sorting stations who had no known contact with opened letters became victims. It is thought that the automated sorting equipment used by the U.S. Postal Service damaged the envelopes and released

anthrax spores into the facilities.

The FBI and other law enforcement authorities are investigating these events as criminal acts. CDC is working with the U.S. Postal Service to address the risk for anthrax infection among postal employees, and to prevent further passage of pathogens through the mail. Further background and up-to-date information on these matters is available through CDC at its bioterrorism website <http://www.bt.cdc.gov>.

Handling Suspicious Mail

Watch for and do not open suspicious-looking packages/letters. The government warns against the following: inappropriate or unusual labeling; no return address or a return address that differs from the city or state on the postmark; excessive binding materials such as tape and string; handwritten or poorly typed address; excessive postage; address without the name of a specific person; and restrictive markings such as "Do not X-ray," "Personal," or "Confidential."

What is Anthrax?

B. anthracis is a Gram-positive but non-motile, spore-forming bacterial rod. There are three pathogenic components of *B. anthracis*: edema toxin, lethal toxin and a capsular antigen. Human anthrax has three major clinical forms depending on the route of exposure: cutaneous, gastrointestinal and inhalation. Left untreated, all forms can lead to death, although death is rare with cutaneous infection.

Anthrax most commonly occurs in wild and domestic lower vertebrates such as cattle, sheep, goats, camels, antelopes, and other herbivores in agricultural areas. Humans can contract it when exposed to infected animals.

Indigenous areas for anthrax include Africa, Asia, the Caribbean, Central and South America, Eastern and Southern Europe and the Middle East. When anthrax has been

contracted by Americans, it was usually due to occupational exposure to infected animals or animal products imported from other countries. However, anthrax in wild livestock has occurred in the U.S.

In order for anthrax organisms to cause cutaneous infections, they must be rubbed into abraded, damaged skin. To cause inhalation infections, they must be inhaled as a fine, aerosolized mist. For these reasons, contracting anthrax via contaminated mail is considered to be an anomaly and not a danger to the general population.

In order for anthrax to be effective as a mass bioterrorism agent, it must be aerosolized into very small particles and spread in massive amounts over a large area. This is one of the reasons why airplanes, helicopters and blimps were forbidden to fly over open sports stadia after anthrax spores were discovered to have contaminated mail.

According to CDC, the spread of anthrax from person-to-person is extremely unlikely. Contracting the infection is not a concern in managing or visiting patients with anthrax. However, as a precautionary measure, physicians are ordering prophylactic doses of antibiotics for caregivers and family members.

Signs and Symptoms of Anthrax Infection

While symptoms of anthrax infection vary depending on how it was contracted, symptoms usually occur within one week. **Cutaneous anthrax** (the most common form reported) occurs after skin contact with contaminated meat, hides, leather or wool from infected animals. The incubation period is from one to 12 days. It initially mimics a small insect bite, advancing to blistering in one to two days, followed by an open sore, 1 to 3 cm in diameter, with a characteristic black necrotic (dead tissue) area at the center.

These lesions are usually painless. However, the patient may

experience fever, headache, malaise and localized enlarged lymph glands. CDC estimates that approximately 20 percent of patients with untreated cutaneous anthrax infection will die. However, with proper antibiotic treatment, deaths are rare.

The **inhalation form of anthrax** is the most lethal. It is estimated that 4,000 to 5,000 anthrax spores must be inhaled to cause a clinical infection. The incubation period has not yet been fully determined, and is considered to be one to seven days, but may be as long as two months.

Early symptoms resemble those of the common cold: sore throat, mild fever, muscle aches and pain, and malaise. These progress to severe respiratory distress due to enlarged regional lymph glands compressing the trachea. Respiratory failure, cyanosis, shock and death can occur within 24 to 36 hours. The fatality rate for untreated cases of inhalation anthrax is estimated to be 90 percent and greater.

The specific symptoms that persons should watch for are: fever (greater than 100°F); flu-like symptoms such as cough, fatigue, muscle aches/pain, nausea, vomiting and/or diarrhea; and sores on the face, arms or hands.

Treatment

At the time the outbreak of anthrax infections due to handling contaminated mail occurred, there was only limited clinical experience to validate the agent of choice for treatment, mainly because the disease was relatively rare. For years, penicillin G procaine, then later ampicillin, had been approved for use in treating inhalation anthrax. However, preliminary data indicated that *B. anthracis* isolates from New York, West Palm Beach and Washington, D.C. were able to produce both penicillinase and cephalosporinase. Therefore, the current advice from CDC is that penicillin and cephalosporin deriva-

tives be reserved for patients in whom the agents of choice, ciprofloxacin or doxycycline, are contraindicated.

For **inhalation anthrax infection**, CDC's recommended protocol for adults is 400mg of ciprofloxacin intravenously every 12 hours or 100mg of doxycycline intravenously every 12 hours initially. When appropriate, patients should be switched to oral therapy with doses of 500mg of ciprofloxacin BID or 100mg of doxycycline BID.

Because of the potential persistence of spores after aerosol exposure and unknown incubation period, therapy should be continued for two months. Pediatric doses are 10-15mg/kg for ciprofloxacin (preferred) or 2.3mg/kg for doxycycline. Neither of these antibiotics is generally used in children, but in this instance the benefit/risk ratio is heavily in favor of their use.

Other agents that have shown therapeutic activity against anthrax are chloramphenicol, clarithromycin, clindamycin, imipenem, rifampin and vancomycin. Steroids are used adjunctively for patients with severe edema or meningitis.

The protocol for treating **cutaneous anthrax infection** is oral therapy with ciprofloxacin 500mg BID, or doxycycline 100mg BID, for adults. Continuous therapy for 60 days is recommended. Pediatric dosing uses the same schedule as with inhalation anthrax infection.

Prophylactic oral antibiotic use for post-exposure of inhalation anthrax is warranted. Fluoroquinolones (ciprofloxacin), tetracyclines (doxycycline), and penicillins (amoxicillin) are the current agents of choice. Children may be dosed with 10-15mg/kg of ciprofloxacin twice daily, but changed to amoxicillin as soon as susceptibility has been confirmed. Resistance of *B. anthracis* to these antibiotics is rare.

The FDA and other health authorities strongly discourage persons from purchasing antibiotics over the Internet from foreign "cyber pharmacies" to self-medicate for prevention of anthrax infection or to

keep on hand "just in case." This suggestion is based on the concept that unnecessary use of antibiotics exposes patients to serious risks of adverse effects without any potential benefit.

Interestingly, FDA has issued a warning to consumers against obtaining any prescription drug over the Internet citing that the product could be contaminated and harmful; counterfeit and not contain an active ingredient; contain the wrong dose; without adequate screening by a health care professional; unsafe or inappropriate; no access to a health care professional if a serious side effect occurs; or no product may be received after payment is sent.

Also of interest is that when FDA discovers foreign Internet vendors are offering to sell prescription drugs to Americans (with ciprofloxacin, 11 such vendors have been identified), the agency sends "cyber letters" to inform them that the agency is taking actions to halt potentially illicit drug sales to U.S. citizens. More information on this effort can be found on FDA's website at <http://www.fda.gov/cder/warn/>.

Anthrax Vaccine

A vaccine to protect against anthrax infection is available and routinely used in military personnel deployed to areas of high risk of exposure to the organism when used as a biological warfare weapon. The immunization consists of three subcutaneous injections given two weeks apart, followed by three additional subcutaneous injections at six, 12 and 18 months. Annual booster shots of the vaccine are recommended thereafter.

At this time, routine vaccination against anthrax is not recommended for the general public to prevent the disease, and it is not easily available for this purpose. Rather than mass immunization with the vaccine, prophylactic oral treatment with ciprofloxacin or doxycycline (discussed earlier) is considered to be adequate for household contacts, friends or coworkers unless they

were also exposed to the same source of infection as the diagnosed victim.

At the time of preparation of this lesson, the federal government is making plans for stockpiling and mobilizing the vaccine in case of a generalized bioterrorist attack with anthrax. When the vaccine is available in greater supply, it, plus an antibiotic, might be the most effective regimen.

Patient Counseling for Ciprofloxacin

While ciprofloxacin is available generically elsewhere around the world and the FDA has approved several generic versions, only Cipro is available in the U.S. because its manufacturer is challenging their release to the market based on patent rights violations. Therefore, this section will refer to *Cipro* rather than *ciprofloxacin*.

Patients for whom Cipro is being prescribed should tell their doctor if they have had an allergic reaction to any form of quinolone antibiotic or have a history of convulsions. They should also tell their doctor if they are taking theophylline due to a potential drug interaction. Di- and trivalent cations such as aluminum, bismuth, iron, magnesium, calcium or zinc may interfere with the absorption of quinolone antibiotics. These products should be taken six hours before or two hours after quinolone antibiotics.

Each dose should be taken with a full glass of water or other liquid (but not milk or yogurt), and lots of fluids should be ingested during therapy. However, excessive intake of caffeine-containing beverages is not recommended. The manufacturer states this medicine can be taken regardless of meals, but two hours after a meal is preferred.

All doses should be taken every day, possibly for as long as 60 days. If patients forget to take a dose, it should be taken as soon as possible unless it is almost time for the next dose. They should not double the dose unless told to do so by their doctor.

Table 1
Components of the National Pharmaceutical Stockpile

1. 12-hour Push Package

- contains eight fully stocked packages
- positioned in environmentally controlled, secured warehouses
- ready for immediate deployment
- will reach any affected area within 12 hours
- preassembled set of supplies, drugs and medical equipment
- each package consists of 50 tons of material
- intended to address mass casualty incident
- will permit emergency medical staff to treat a variety of agents since actual threat may not have been identified at the time the package was deployed

2. Vendor Managed Inventory (VMI)

- deployed if incident requires larger or multi-phased response
- shipped within 24 to 36 hours of Push Package
- comprised of drugs and supplies "tailored" to specific suspected agent or combination of agents

Some patients experience drowsiness when taking a quinolone, so caution should be exercised when driving or performing tasks that require alertness until they know how they react to Cipro. Photosensitivity has been seen in patients taking quinolones. Therefore, patients taking Cipro should avoid excessive sunlight and tanning booths, use a sunscreen (minimum SPF 15), or wear protective clothing if it makes them sensitive to sunlight.

Side effects reported at the 5 percent or higher level are: stomach pain, headache, nausea and vomiting and/or diarrhea. If diarrhea is a problem, the patient should call the doctor before self-medicating with OTC antidiarrheal products. Excessive diarrhea may be the result of overgrowth by nonsusceptible organisms.

The quinolones have been implicated in causing or aggravating

tendonitis. Quinolone manufacturers warn patients to stop taking the drug and call their doctor immediately if they experience pain, inflammation or rupture of a tendon while taking it. They also advise patients to call their doctor right away if they experience an allergic reaction such as irregular or fast breathing, skin rash, hives or itching.

Patient Counseling for Doxycycline

Patients for whom doxycycline is prescribed should tell their doctor if they have had an allergic reaction to any form of tetracycline antibiotic or have liver disease. Di- and trivalent cations such as aluminum, bismuth, iron, magnesium, calcium or zinc may interfere with the absorption of doxycycline. Products containing them should be taken at least two hours before or after the antibiotic.

Each dose should be taken with a full glass of water. The last dose of the day should be taken at least an hour before going to bed due to the possibility of esophageal irritation if doxycycline is not swallowed properly.

All doses should be taken every day, possibly for as long as 60 days. If patients forget to take a dose, it should be taken as soon as possible unless it is almost time for the next dose. They should not double the dose unless told to do so by their doctor.

Photosensitivity, which develops as exaggerated sunburn, occurs in some patients taking tetracycline (and its derivatives). Therefore patients taking doxycycline should avoid excessive sunlight and tanning booths. Using a sunscreen (minimum SPF 15) and wearing protective clothing during normal exposure may prevent this from happening. Manufacturers state that patients should stop taking the product and contact their doctor at the first sign of sunburn.

Side effects reported at the 5 percent or higher level are: stomach upset, rectal itch, nausea and vomiting and/or diarrhea.

If diarrhea is a problem, the patient should call the doctor before self-medicating with OTC antidiarrheal products. Excessive diarrhea may be the result of overgrowth by non-susceptible organisms.

Manufacturers state that patients should call their doctor right away if they experience an allergic reaction such as irregular or fast breathing, skin rash, hives or itching.

The Plan for Future Bioterrorist Attacks

The terrorist events of 2001 have challenged the government and health care industry because of the possibility of bioterrorist attacks on America, and the need to be more alert and prepared. In addition to anthrax, there are other potential bioterrorism candidates: botulism, pneumonic plague, smallpox and tularemia.

A National Pharmaceutical Stockpile has been developed, the mission of which is "to ensure the availability of life-saving pharmaceuticals, antibiotics, chemical interventions, as well as medical, surgical and patient support supplies, and equipment for prompt delivery to the site of a disaster, including a possible biological or chemical terrorist event anywhere in the United States."

At press time, the stockpile reportedly had been assembled, ready for deployment via air transport to any county in any state for use by local health officials and health care volunteers. The basic components of the National Pharmaceutical Stockpile are listed in Table 1.

Continuing Education Quiz

This month's questions are taken from the article on "Patient Counseling: Biological Terrorism." Circle your answers to the following questions and mail the entire page to Maryland Pharmacist CE, 650 W. Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members \$ 10.00). The completed quiz for this issue must be received by 1/15/05. A continuing education certificate for one and one-half contact hours (0.15 CEUs) will be mailed to you within six to eight weeks. Please type or print clearly. ACPE# 129-144-02-001-H01.

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1. According to the CDC as of November 2001, the number of deaths associated with inhalation anthrax contracted from contaminated mail was:

- a. none.
- b. 4.
- c. 17.
- d. 236.

2. In nature, anthrax may be contracted by humans from which of the following sources?

- a. Rats
- b. Birds
- c. Herbivores
- d. Mosquitoes

3. All of the following are true about cutaneous anthrax infections EXCEPT:

- a. the incubation period is one to 12 days.
- b. it initially mimics a small insect bite.
- c. it advances to blistering followed by an open sore with dead tissue at its center.
- d. it is passed from person to person via serum that escapes from the blisters.

4. Early symptoms of the inhalation form of anthrax infection most closely resemble those of:

- a. a common cold.
- b. left-sided heart failure.
- c. emphysema.
- d. scarlet fever.

5. Because of the persistence of anthrax spores after aerosol exposure, therapy for inhalation anthrax should be continued for:

- a. two days.
- b. two weeks.
- c. two months.
- d. two years.

6. FDA and other authorities are telling the public that purchasing antibiotics over the Internet is a:

- a. bad idea and discourage it.
- b. good idea and encourage it.

7. Patients allergic to which of the following groups of antibiotics should tell their doctor before Cipro is prescribed.

- a. Macrolides
- b. Tetracyclines
- c. Penicillins
- d. Quinolones

8. Proper counseling for patients taking Cipro include all of the following EXCEPT:

- a. avoid excessive exposure to sunlight and tanning booths.
- b. take each dose with yogurt or a full glass of milk.
- c. doses can be taken regardless of meals, but two hours after meals is preferred.
- d. if diarrhea becomes a problem, call your doctor before self-medicating with an OTC antidiarrheal.

9. Proper counseling for patients taking doxycycline include all of the following EXCEPT:

- a. avoid excessive exposure to sunlight and tanning booths.
- b. take the last dose of the day just before going to bed with a full cup of warm milk.
- c. call your doctor right away if you experience irregular or fast breathing, skin rash, hives or itching.
- d. if diarrhea becomes a problem, call your doctor before self-medicating with an OTC antidiarrheal.

10. All of the following describe the National Pharmaceutical Stockpile "Push Packs" EXCEPT:

- a. ready for immediate deployment to reach affected area within 12 hours.
- b. each package contain 50 tons of material.
- c. contain preassembled sets of supplies, drugs and medical equipment.
- d. contain drugs and supplies tailored to a specific bioterrorism agent.

CORRECTION: The correct ACPE number for Patient Counseling: Management of Sore Throat which appeared in the Jan./Feb./Mar. 2002 issue of the Maryland Pharmacist is 129-144-01-011-H01.

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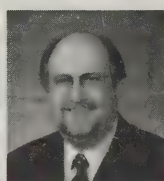


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The "Bowl of Hygeia"



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Maryland



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Scot M. Silber
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Rubén Kravitz
Virginia



John S. Oftabro
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Edward F. Dillon
Washington, D.C.



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Jerald A. Sveum
Wisconsin



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Wyoming

Wyeth Pharmaceuticals takes great pride in continuing the "Bowl of Hygeia" Award Program developed by the A. H. Robins Company to recognize pharmacists across the nation for outstanding service to their communities. Selected through their respective professional pharmacy associations, each of these dedicated individuals has made uniquely personal contributions to a strong, healthy community which richly deserves both congratulations and our thanks for their high example.

MARYLAND Pharmacist

VOLUME 79 No. 1

Maryland Leadership Elections

*"Statements of the Candidates
& Official Ballot"*

MPhA Pharmacy News

"March Newsletter"

The MPhA Awards

*"Recognizing Pharmacy Excellence -
Award Nomination Form"*

VOTE
VOTE
VOTE

**The 2003
Maryland Pharmacists Association
Leadership Elections**

Maryland Pharmacists Association

650 W. Lombard Street
Baltimore, MD 21201
(410) 727-0746

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Maryland Pharmacist

The Official Publication of the Maryland Pharmacists Association

President's Address 5
"Mid-year Report"

Director's Column 7
"When an Ugly Duckling becomes a Swan"

2003 Maryland Leadership Election 9
"Statements of the Candidates"

Official Ballot 13

Recognizing Pharmacy Excellence 16
"The 2003 MPhA Awards Nomintion Form"

RemiFemin 19
"Safe Alternative for Memopausal Symptoms?"

MPhA Pharmacy News 21
"March Newsletter"

Drotrecogin Alfa (Xigris) 26
"In the Treatment of Severe Sepsis"

Continuing Education 33
Patient Counseling: " Xyrem in the Treatment of Narcolepsy"

Advertiser's Index

Advocate Rx Solutions . . 12
Mayer & Steinberg 32
McKesson 38
Medicine Shoppe 31
PEAC 31
Pharmacists Mutual 28
RPh on the go 40
Shreddit 12

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PRESIDENT'S MID-YEAR REPORT

It's hard to believe that more than six months have passed since I shared my goals for the year with you last June. I used the acronym of "FUNDS" to describe them. It has been my pleasure to work with our Board of Trustees, a very dedicated group of individuals. This mid-year assessment gives us pride in our accomplishments and serves as a checkpoint to achieving goals not quite finished.

"F" STANDS FOR

FUNDRAISING. The MPhA Foundation has raised \$24,901.00 since June 2002, with an additional \$89,250 promised through pledges. A special thank you to the fundraising committee for their successful efforts on behalf of the MPhA Foundation. A huge part of that success goes to Mayer Handelman who has personally sought commitments from all members, including a special emphasis on past presidents, and current MPhA Board of Trustees members. For the past two years, Mayer has co-chaired the Fund Raising Committee along with Marty Mintz. Now is the time for our fundraising efforts to move to the next level. This includes solicitation of funds from non-profit foundations and philanthropic organizations.

A reception held at the conclusion of the 2002 Mid-Year Meeting served as a major fund raising event to obtain the financial resources to display two museums in a manner that reflected Pharmacy's history and pride. I am very proud to announce that at the 2003 Mid-Year meeting reception, these two museums were showcased. These vintage pharmacies, one depicting an 1890 pharmacy and the other showcasing the profession of Pharmacy from the 1950's, represent the work of many

volunteers who worked diligently to turn a long time dream into reality. Kudos to the Chair of the Building and Property Committee and MPhA First Vice President, Richard Baylis, who spearheaded this work.

"U" STANDS FOR UNITE. The MPhA Board of Trustees has continued to support the Maryland Pharmacy Coalition (MPC). This coalition was formed to promote and strengthen the need to coordinate efforts among all facets of Pharmacy and to provide a strong, unified voice. The MPC was very active during National Pharmacy Week in October. They displayed a banner which hung across Light Street in downtown Baltimore. The banner read: *National Pharmacy Week, Pharmacists Promote Medication Safety, The Maryland Pharmacy Coalition.*

The MPC sponsored its third annual Maryland Pharmacy Legislative Day on Wednesday, March 5, 2003. The day began with a continental breakfast followed by a legislative briefing. The bulk of the day was spent visiting legislators and dialoging with them about concerns regarding legislation affecting various practice settings.



Paul R. Holly, President

"N" STANDS FOR NUMBERS.

Not only do we want to increase membership, but we want to retain current members. Membership has increased from 799 in December, 2000 to 977 in December 2002. A large part of this is the efforts of the Membership Committee chaired by Ginger Apyar and the work of Gary Worth, Giant Pharmacies, and MPhA Board of Trustees member. In an innovative and unprecedented commitment by Giant Pharmacies, every Giant Pharmacy Manager is a member of MPhA. Giant Pharmacies commitment to underwriting the cost of membership for its Pharmacy Managers is a strong endorsement for the value of professional association membership. The membership committee is also soliciting this level of commitment from other chain pharmacies. We are also pleased to announce that as of February, 2003, we have 85 University of Maryland, School of Pharmacy students as members of MPhA.

D” STANDS FOR DIRECTION.

What better way to chart an association’s direction than to utilize the knowledge base of past leaders. The Past Presidents Council is comprised of all living MPhA past presidents who are interested in continuing to share their leadership and expertise with this association. The purpose of this Council is to provide direction and guidance to the MPhA Board of Trustees.

Fifty percent of the past presidents attended a meeting facilitated by Past President Murhl Flowers. A frank discussion took place, the highlights of which were budget concerns and membership recruitment. Based upon their valuable past experiences, insight into Pharmacy, history of association work and pharmacy leadership, these past presidents have planned a dinner meeting scheduled for this spring to continue a dialogue on these topics and to offer ideas for moving MPhA forward.

“S” STANDS FOR SHADOWING, AS IN JOB SHADOWING AND

MENTORSHIP. My strong believe in promoting the Pharmacy profession has always been to work one-on-one with a young person. Elementary school children often want to be policemen or fire fighters because of the experiences they have had, first hand, of visiting a police station or fire station. Last year I had two students shadow me for a day. One was in junior high school and the other was in high school. Both were surprised at the various interactions with other health care team professionals for the overall patient welfare.

This year, during National Pharmacy Week, several of our members volunteered to have students shadow them. What better way to showcase pharmacy then to have a young person actually spend time with you seeing, first hand what the profession involves. A huge thank you to those who participated in this activity; you’ve made a difference in a young person’s life with regards to the outlook of Pharmacy as a career.

“FUNDS” – our accomplishments are many but there is always more work to be done. We are continuing to stay the course and fulfill our goals. Some of our dreams have become reality. There are more dreams yet to be realized.

In conclusion, I wish to express my sincere appreciation to the Board of Trustees for their cooperation, hard work and commitment to keeping Pharmacy in Maryland, a strong, viable and respected profession. I also want to thank our Executive Director, Howard Schiff, and office team, Elsie Prince, Office Manager and Rosa Edwards, Administrative Assistant. Without all of their help, hard work and dedication, we could not have accomplished our goals to this point. Let us continue to dream. The future of Maryland Pharmacy is in our hands.



Howard Schiff
Executive Director

There have been few times in our lives when we see an ugly duckling really become a swan. This is one of those times. The lower level (we can no longer call it a basement) of the Kelly Building fits this metaphor. It wasn't until I saw how beautiful the lower level was, that I realized how ugly it had been.

Going from the drab and should-be-renovated main floor down the steps into the lower level is a wonderful surprise because of the great contrast. The room itself is far removed from what it was three months ago. New floors, walls, and lighting brighten up the area and allow for the museum to be properly displayed. The contractor did a great job!

The 1890s pharmacy has beautiful cabinetry. One can see the hand carving and admire the artistry. Many of the artifacts displayed are very old. Glass bottles, hand blown, some with glass labels, are products of that era.

Kelly Memorial Building

The 1950s Arbutus Pharmacy, donated by the estate of pharmacist Daniel Mendelsohn, has artifacts from the 40s through the late 60s, complete with a soda fountain and original ice cream menu. The soda fountain has been hooked up—water only—to complete the display. *Would you want a sundae for 30 cents?*

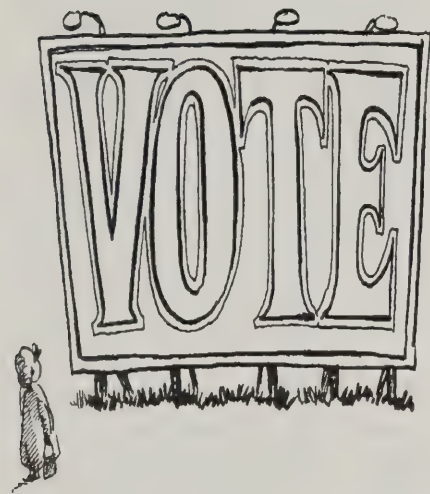
The lower level and the displays open new possibilities. It's obviously a place we want people to see. What remains now, is to bring the main floor up to "snuff." First Vice-president Dick Baylis and his crew did a great job but the work is only half done. Your contributions allowed the MPhA Foundation to bring the lower level to respectability; now it's time to do the same for the main floor. If you haven't yet pledged your support, please do so today. If you have, please honor your pledges with your payment. And, by all means, stop by to see the Kelly Building and its museum displays.



Kelly Memorial Building



STATEMENTS OF THE CANDIDATES



Phil Cogan - Treasurer

I have been a member of the Maryland Pharmacists Association for approximately 30 years. My allegiance to the Association has been demonstrated over that period in many ways. I have served in every elective office of the Association except Treasurer, and I have chaired many of the standing committees of the Association. Currently, I am the Chair of the Law Book Committee and serve as one of the two MPhA representatives on the Maryland Board of Pharmacy Bio-Terrorism Task Force.

While the most recent MPhA administration has made major progress toward putting the Association on a firm financial footing, there is still much that can be done to improve its financial outlook. I would like the MPhA to adhere to a realistic, but strict budget. I support the MPhA Foundation, but would like to see a greater separation of the Foundation from the financial matters of the Association. I favor greater emphasis on non-dues revenue and conservative investments of the Association's financial assets.

I have attended most of the Association's Board of Trustees meetings over the past five years, so I have an understanding of the issues facing the Association. I take seriously the fiduciary responsibility of the Treasurer and would be a strong and vocal advocate for the membership regarding how the funds of the Association will be spent.

Donna Jean Hazel - Trustee Seat #1

I graduated from Duquesne University in 1979 with a B.S. in Pharmacy. I have worked with Rite Aid Corporation since 1979. I have held various positions with Rite Aid,

from staff pharmacist, Pharmacy Supervisor, Pharmacy Development manager, Recruiter and now as a Pharmacy Manager of the Finksburg Store.

It would be an HONOR for me to serve the MPhA.

Butch Henderson, P.D. - Trustee Seat #1

As a current trustee, I have been privileged to see the work that has been accomplished over the last couple years, and I will tell you that the association has been busy. It is exciting to see the combined efforts of pharmacists from different practice settings working together to promote pharmacy in Maryland.

As pharmacy director for a small chain, I still spend time "on the counter" filling prescriptions and counseling patients. I see the daily challenges that face pharmacists in the community, and I get frustrated with the external forces that interfere with our practice of pharmacy. We need to continue to move forward in promoting pharmacy, promoting pharmacists, and removing obstacles and distractions that compromise our relationship with our patients and our ability to practice. We need to promote technology and other mechanisms that will enhance our ability to dispense prescriptions. We need to work with PBMs to develop more logical and practical resolutions to conflicts which pharmacists are burdened with on a daily basis.

In summary, it would be an honor to serve as a trustee and to be an integral part of an association that is truly doing things to promote our profession and to promote our pharmacists in Maryland.

Matt Shimoda - Second Vice President

As we all know our profession is in a continual and quite often volatile "state of affairs". I believe that we have made many great strides recently to move forward at a pace that most of us have not seen. The Maryland Pharmacy Coalition, Collaborate Practice, the growing role of Pharmacists in the uncertain world that we live in, the growing concern of the shortage of Pharmacists today and tomorrow, and the day to day changes in Health care.

I have served on the Board of Trustees for the Maryland Pharmacists Association for two terms, President-elect of the Alumni Association University of Maryland School of Pharmacy, Board of Visitors for the School of Pharmacy, and have been active in many other facets of Pharmacy for the past 20 years. If elected to this position I will continue to work on the difficult issues that face us. I feel that Pharmacy is at one of the many "crossroads" in our profession and it will take active participation to continue the momentum. I would ask all Pharmacists to open their minds to the changes we face and become part of the solution.

**Kathryn K. Fader -
Trustee Seat #2**

Professionalism has always been a hallmark of pharmacy practice. In seeking a position on the Board of Trustees, I look forward to promoting the pharmacist's ability to practice with dignity and under the strong code of ethics that we each feel is so important to our profession. The push for high volume turnover, third party involvement at our prescription counters, the decline in ethical expectations from other health professionals must not take over our practices as caring providers.

I am a 1970 graduate of Idaho State University's College of Pharmacy. My 32 years of pharmacy practice in Maryland have spanned from hospital, both inpatient and outpatient, to independent retail practice, to my current position with Target Pharmacy.

**Cherokee Layson-Wolf, Pharm.D. -
Trustee Seat #2**

Cherokee Layson-Wolf, Pharm.D. is an assistant professor with the University of Maryland, School of Pharmacy, of which she is a member of the Class of 2000. She completed an ASHP-accredited pharmacy practice residency with an emphasis in community care with the Virginia Commonwealth University, School of Pharmacy and Ukrop's Pharmacy in Richmond, VA.

As a faculty member, her main focus is the development of patient care services at NeighborCare Professional Pharmacies. Dr. Layson-Wolf advises several student organizations, including the Academy of Students of Pharmacy (ASP), the student organization of the American Pharmaceutical Association. She has served MPhA by serving as a delegate to the House of Delegates at the APhA Annual Meeting in Philadelphia, PA in 2002 and as an active member of the Drug Therapy Management Task Force committee by chairing the protocol template

development subcommittee.

Personal statement:

During my residency in Richmond, VA, I was able to participate in a variety of patient care activities that really opened my eyes to great potential that pharmacists have in providing care to their patients. When I was either providing cholesterol screenings or flu shots, I saw that these patients really valued the services. Pharmacists' scope of practice vary greatly from state to state, and those with limited ability continuously struggle to enhance their roles.

Even through pharmacy school, I recall the challenges that Maryland pharmacists face in advancing the profession. The possibility of collaborative practice allowed pharmacists the opportunity to demonstrate our ability to make great contributions to patient care. The Maryland Pharmacists Association, along with leadership from other groups in the state, was able to see the fruits of their labor when the Collaborative Drug Therapy Management legislation was finally passed in 2002. I feel that this great accomplishment is just the beginning of our potential as pharmacists.

With all these advancements, it is also important to reinforce the impact of these advancements to students in pharmacy, so they too can also grow a passion and commitment to the profession of pharmacy. Through my future involvement with MPhA, I plan to carry on its mission of representing Maryland Pharmacists and also to motivate pharmacy students to become active and contributing members of their state pharmacy association.

**Harry Finke Jr., P.D. -
Trustee Seat #3**

Since my graduation in 1977, I strongly believed that the pharmacy profession could be practiced clinically even in the community setting. My goal has always been to

give back to the profession what it gave to me, a gratifying career. I have always tried to improve and be pro-active in the profession so that those entering after me could have a more gathering and challenging profession. There has been much improvement in information gathering and procession and educational standards but what is still deficient is the profession's inability to correct the inequity and disparity that exists between pharmacy and the HMOs, PPOs, PBMs and Medicaid.

My goal, if elected, is to be pro-active in making the playing field equal by flexing professional muscle through MPhA by striving to have regulations passed and accountability for all the insurance providers. There are many unanswered questions concerning reimbursements, for time, product, and contracts that are force fed to pharmacists without any legal counseling and the lack of a conduit to bring about the necessary changes to resolve these unanswered questions. I will work diligently to use MPhA as a conduit to exert pressure to the insurance providers to be accountable and to ambitiously bring about a more cohesive profession so we can all benefit now and in the future. Yes, fellow pharmacists, I am back...

**Stephen Weininger -
Trustee Seat #3**

My name is Stephen Weininger. I graduated from the University of MD School of Pharmacy in 1991. I have been a community pharmacist for eleven years and currently own Mt. Vernon Pharmacy in Baltimore City. I am member of AZO Pharmaceutical fraternity, MPhA, and NCPA. I graduated right smack in the middle of my class, but have always had a desire to own a community pharmacy. I'm living proof that diligence, compassion, and a friendly smile are the recipes for success. My most impressive achievements are my wife, Harriette, and my three

children.

The most pressing challenge community pharmacists face are job burn-out. There never seems to be enough time to spend counseling patients. Higher prescription volumes make me think of the "I Love Lucy" episode where she was trying to box chocolates on the conveyor belt. Hopefully, pharmacists are not shoving pills in their mouths like Lucy was shoving chocolates. The stress is compounded when pharmacists and their support staff are forced to become formulary police for PBMs and insurance companies. What's that joke? "How many—does it take to screw in a light bulb? or is it, "How many calls does it take to fill a prescription?" Imagine filling an inexpensive prescription for cash that required no phone calls and the senior citizen didn't make you feel like you were taking away their grocery money. Alas, no one prescribes Penicillin anymore.

What are the solutions? Perhaps it lies in excellent support staff. Maybe pharmacy law will evolve into the 21st century. It tickles me that a technician can not take a new prescription over the phone, yet it is completely permissible for a doctor to leave a voice recording on a pharmacy computer? Is it permissible for a technician to then transcribe that recorded message onto paper? Perhaps it lies in technologic innovations. Imagine standardized forms that allow the faxing of formulary prescription rejections to doctors and insurers. Better yet, imagine when your computer system can do this automatically. Filling a prescription is evolving into a lengthy tedious process.

Unfortunately, I do not have the answers to these problems. My father, Herb Weinner, was a pharmacist. I am a pharmacist today because of my admiration for him. To this day, I try to live up the legacy he left. He was well respected in his community. He was funny and always had great

stories to bring home from work at Park Avenue Pharmacy. If I can solve just a few of these problems, maybe my children might want to follow in my foot steps.

Thank you for considering me as a trustee for MPhA.

Douglas W. Campbell, R.Ph., B. Sc.
Trustee Seat #4

I would like to serve on the Board of Trustees of the Maryland Pharmacists Association (MPhA) to help improve the practice of pharmacy in Maryland. I would like to see MPhA grow in membership and improve and expand the services it offers Maryland's pharmacists. I currently work in various pharmacy settings all over the state. I hope to take some of the many concerns I hear from many pharmacists to MPhA for discussion. I look forward to serving MPhA in a more direct way, after my many years of past membership, and I hope I can make a positive difference for the improvement of pharmacy in Maryland.

Henry Leikach, R.Ph. -
Trustee Seat #4

It is an honor to be considered for the position of Trustee for MPhA. I appreciate the opportunity to assist in this capacity. I graduated from the University of MD School of Pharmacy in 1969. I have served in several leadership roles in pharmacy organizations over the years. I am a past President of the University of Maryland School of Pharmacy Alumni Association and still volunteer on the Executive Board. Currently, I am the President of the Kappa Alumni Chapter of Alpha Zeta Omega Pharmacy Fraternity. Our organization holds CE programs monthly for members and guests and is currently planning the fraternity's National Convention to be held in Baltimore this summer. As president of this local organization, I have had an opportunity to meet many different pharmacists and talk with them about

the needs of different areas of pharmacy. My employment background is in independent and chain community pharmacy and I presently work at Catonsville Pharmacy with my son, Neil.

As a trustee for MPhA, I would be an active part of the board. I understand that it is important to be present for the monthly meetings and to attend the functions sponsored by MPhA. I will support the various committees run by MPhA and assist these committees in their functions. Thank you for your consideration and I hope to have the opportunity to serve the pharmacists in Maryland.



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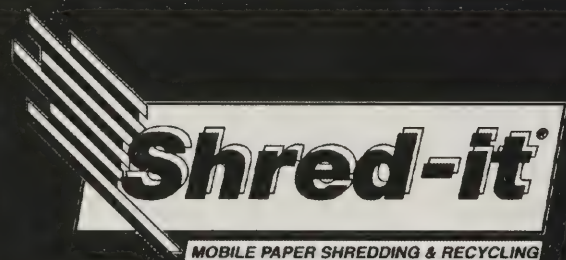
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2003 Maryland Leadership Elections Official Ballot

Please select the candidate you believe will best fulfill the duties of the office by checking the box appearing beside their name.

Maryland Pharmacists Association Officers

Second Vice President

☐ Matt Shimoda, Pharm.D.

Treasurer

☐ Phil Cogan, R.Ph.

Please select the candidate you believe will best represent you as a member on the Board of Trustees by checking the box appearing beside their name.

Maryland Pharmacists Association Board of Trustees

Trustee Seat # 1

- ☐ Donna Jean Hazel, R. Ph.
- ☐ Butch Henderson, P.D.

Trustee Seat # 2

- ☐ Kathryn K. Fader, R.Ph.
- ☐ Cherokee Layson-Wolf, Pharm.D.

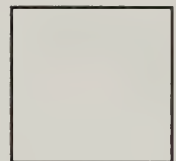
Trustee Seat # 3

- ☐ Harry Finke, Jr., P.D.
- ☐ Stephen Weiner, P.D.

When completed, seal and return your self-mail ballot to the Maryland Pharmacists Association, *received by Friday, April 25, 2003*. For questions, please call MPhA at 800-833-7587.

**Only official ballots from the “Maryland Pharmacist”
journal will be accepted—no photocopies.**

Fold



2003 Maryland Leadership Elections

Maryland Pharmacists Association
650 W. Lombard Street
Baltimore, MD 21201-1572

Fold



2003 121st Annual Convention, June 7 - 10 2003

SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
1	2	3	4	5 	6  CE'S	7  PRESIDENT'S BBQ COOKOUT
8 CE'S & HOD MEETING  CRAB FEAST BERLIN FIREHALL	9 CE'S & HOD MEETING TRADE SHOW & JOB FAIR AWARDS RECEPTION & BANQUET	10 CE'S 	11	12 	13  FLAG DAY	14
15 FATHERS DAY 	16	17	18	19	20 SUMMER BEGINS 	21
22	23	24	25	26	27	28
29	30					



Recognizing Pharmacy Excellence

The 2003 MPhA Awards

Each year, the Maryland Pharmacists Association recognizes professional excellence through a series of awards. To nominate a pharmacist for one of the awards described below, complete the Official Award Nomination Form. The forms should be submitted to: Award Nominations, c/o Maryland Pharmacists Association, 650 West Lombard Street, Baltimore, Maryland 21201-1572.

All nominations will be reviewed by the Past Presidents Council who is responsible for selecting the award recipients. The decision of the Council is final. Award recipients will be notified in advance of the award's presentation at the 121st Annual MPhA Convention.

For consideration, all nominations must be received no later than *Friday, April 11, 2003*.

- **Pharmacists Mutual Distinguished Young Pharmacist Award**
Awarded to a pharmacist who graduated within the past ten years and has made a significant contribution to the profession through service to a local, state or national pharmacy organization. *Who is Eligible:* Any MPhA pharmacist member who graduated from pharmacy school in 1994 or after.
- **Maryland Pharmacists Association Honorary President**
An honorary position on the Board of Trustees given to a person, not necessarily a pharmacist, who has worked for the MPhA or Maryland Pharmacy over a long period of time. *Who is Eligible:* Any long standing contributor to the profession or the Association.
- **Seidman Distinguished Achievement Award**
Created to honor the major impact on the pharmacy profession by Henry Seidman, this award is presented for outstanding service by a Maryland pharmacist to the pharmacy profession during *either* the past year or over a period of years. *Who is Eligible:* Any MPhA pharmacist member who meets the criteria of the award.
- **Wyeth-Ayerst Bowl of Hygeia Award**
The Bowl of Hygeia recognizes a pharmacist who has performed outstanding services to the community in any area, with a particular emphasis on non-pharmacy contributions. *Who is Eligible:* Any MPhA member pharmacist who has not already received the Bowl of Hygeia.
- **Elan Innovative Practice Award**
Established in 1993, this award aims to recognize forward-thinking pharmacists who have expanded their practices into new areas. Any practicing pharmacist member within the geographic area who has demonstrated innovative pharmacy practice resulting in improved patient care. *Who is Eligible:* Any MPhA pharmacist member who meets the criteria of the award.

Maryland Pharmacists Association

Award Nomination Form

To nominate a Maryland pharmacist for one of MPhA's annual "Recognizing Pharmacy Excellence" awards, this form must be completed and returned to the Maryland Pharmacists Association no later than **Friday, April 11, 2003**. All nominations will be held in strictest confidence by the MPhA Past Presidents Council, which is responsible for selecting the award recipients. The decision of the Council is final. Award recipients will be notified in advance of the presentation of the award.

Please consider the following nominee for:

☐ **Pharmacist Mutual Distinguished Young Pharmacist Award**

Nominee _____
Home Address _____
City/State/Zip _____
Current Place of Employment/Practice _____
Telephone _____
Work Phone _____
Name of Nominator _____
Nominator's Phone _____

☐ **Seidman Distinguished Achievement Award**

Nominee _____
Home Address _____
City/State/Zip _____
Current Place of Employment/Practice _____
Telephone _____
Work Phone _____
Name of Nominator _____
Nominator's Phone _____

☐ **Elan Innovative Practice Award**

Nominee _____
Home Address _____
City/State/Zip _____
Current Place of Employment/Practice _____
Telephone _____
Work Phone _____
Name of Nominator _____
Nominator's Phone _____

☐ **Wyeth-Ayerst Bowl of Hygeia**

Nominee _____
Home Address _____
City/State/Zip _____
Current Place of Employment/Practice _____
Telephone _____
Work Phone _____
Name of Nominator _____
Nominator's Phone _____

☐ **MPhA Honorary President**

Nominee _____
Home Address _____
City/State/Zip _____
Current Place of Employment/Practice _____
Telephone _____
Work Phone _____
Name of Nominator _____
Nominator's Phone _____

Attach a current resume or curriculum vitae for the nominee that shows their professional and personal achievements. This information is essential for the Past Presidents Council to make its decisions as to which candidates will be recipients of the "Recognizing Pharmacy Excellence" awards. In addition, the nominator should attach a brief letter explaining why the nominee is worthy of receiving this award.

Return the completed form to:

Awards Nominations
c/o Maryland Pharmacists Association
650 W. Lombard Street
Baltimore, MD 21201-1572

Fold

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2003 Awards Nominations
Maryland Pharmacists Association
650 W. Lombard Street
Baltimore, MD 21201-1572

Fold

Is RemiFemin Really a Safe Alternative for Menopausal Symptoms?

By Charlene Hosley, Pharm.D. Candidate

RemiFemin, a popular extract of black cohosh (*Cimicifuga racemosa*), was marketed in Europe since 1956 as an over-the-counter product "for the treatment of symptoms of the climacteric".¹ RemiFemin was originally available as a tincture (an ethanolic extract of the fresh or dried root of black cohosh, 60% by volume).² The formulation changed over the years to an isopropanolic extract of the root, 40% by volume and was later available as a tablet. RemiFemin's exact mechanism of action is unknown since black cohosh contains a variety of components (e.g., triterpene glycosides, flavenoids, isoferulic acids, volatile oils and tannins). The active components are believed to be the triterpene glycosides and isoflavones which were once thought to have estrogenic effects.^{1,2,3}



Black Cohosh

RemiFemin was first manufactured by Schaper & Brummer in Germany and was originally distributed in the U.S. by PhytoPharmica of Greenbay, Wisconsin.¹ The product appeared mostly on the shelves of specialty herbs and vitamin shops. RemiFemin did not have a strong U.S. market until after nearly 40 years of scientific studies. In the early 1990s, the main ingredient of RemiFemin, black cohosh, was shown to be effective and was finally approved by the botanical regulatory body in Germany. In *The Complete German Commission E. Monographs – Therapeutic Guide to Herbal Medicines* black cohosh is approved for the treatment of PMS, dysmenorrhea, and menopausal neurovegetative symptoms. The appropriate dosage for the treatment of menopausal symptoms is 10 to 25 drops of tincture one to three times a day or 1 tablet of RemiFemin twice daily. Therapeutic effects are seen after two weeks of treatment. Gastrointestinal discomfort has been reported as a side effect, while frontal headache, nausea, dilated pupils, and flushed face are signs and symptoms of overdosing. There are no known contraindications to black cohosh, however, the herb is not recommended in pregnancy or lactation, or in

conditions of low blood pressure, because of its hypotensive effects. Its use is restricted to no more than 6 months due to the lack of studies investigating long-term effects.² Under the Dietary Supplement Health and Education Act (DSHEA), dietary supplements that were marketed prior to October 15, 1994, such as RemiFemin and black cohosh, required no proof of safety. As such, the Food and Drug Administration has little authority to regulate either of these products or the claims that manufacturers make for their uses. Deregulation brought about by DSHEA opened the doors wide for the marketing of many over-the-counter herbal products to consumers seeking alternative medicinal treatments.

In March 2001, the pharmaceutical giant, GlaxoSmithKline, bought the U.S. distribution rights for RemiFemin and began widespread marketing of the latest tablet formulation for the relief of menopausal symptoms such as hot flashes, night sweats, nervousness, headaches, and heart palpitations.⁴ RemiFemin suddenly appeared on the shelves of many chain grocery and drug stores. It was also aggressively advertised on the internet, offering the public free samples and "proof" of safety and efficacy with a **disclaimer** for any estrogenic effect. Many people later questioned this change in marketing strategy and felt that GlaxoSmithKline jumped on the profit-making bandwagon in anticipation of pending results from two major studies dealing with hormone replacement therapy (HRT).

In the July 17, 2002 issue of the *Journal of the American Medical Association (JAMA)*, there were two disturbing reports: one from the Women's Health Initiative and the other from a study conducted by the National Cancer Institute (NCI) on estrogen-only therapy (ERT). The first report announced that the Women's Health Initiative study was prematurely cancelled on July 9, 2002 for women who had not had a hysterectomy and were taking a combination of estrogen and progestin. Overall health risks outweighed the benefits. Women taking combined HRT had a 26% increased risk of invasive breast cancer. In addition, the risk of strokes jumped 41% in the combined HRT group, the risk of heart attacks increased 29 percent, and the risk of blood clots in the lungs and deep veins doubled. The NCI study found that women who used estrogen-only therapy for more than 10 years after menopause were at an increased risk for ovarian cancer. It also found that

women taking estrogen-only therapy had a 60% greater risk of developing ovarian cancer than women who did not take estrogen.⁵

According to GlaxoSmithKline, these two reports question HRT's ability to improve women's overall health after menopause on a long-term basis and raise concerns about long-term safety. Women should consider the option of herbal medicines to find relief from menopausal symptoms. They should consider safety, efficacy, and consistency of content when choosing an herbal product. To assist consumers in selecting an appropriate product, the distributor points to a recent study conducted by Liske et al. that showed RemiFemin was estrogen free and relieved mild to moderate menopause symptoms such as hot flashes, night sweats, mood swings, irritability and related occasional sleeplessness.⁵ The only logical choice for women who want to avoid the risks of HRT and still get relief from menopausal symptoms seems to be RemiFemin. Or is it?

Not so well publicized was the fact that Eskehard Liske, the lead author of the RemiFemin safety and efficacy study, is also the head of gynecological research and design at Schaper and Brummer (the makers of RemiFemin), and that the research for Liske's study was fully funded by the manufacturer.⁶ Also not well publicized was the fact that early studies of RemiFemin in Europe were based on two different formulations. Many of the German clinical studies used a daily dose of RemiFemin ranging from 4 to 8 mg triterpines, in the form of 40 mg tablets containing 1 mg triterpines each or 80 drops of liquid RemiFemin. The product currently marketed in the U.S. contains 20 mg of standardized extract and the recommended dose is one 20-mg tablet twice a day or 40 drops of RemiFemin liquid extract per day (half the original recommended German study dose). Most of the German clinical trials as well as even more recent trials of RemiFemin use by breast cancer patients were very poorly designed. They were either uncontrolled, showed no significant difference between the product and a placebo, had inadequate study populations, or contained a mixed population of premenopausal, perimenopausal, and postmenopausal women, and were all 6 months or less in duration.^{1,4,7} The current long-term study being conducted by the National Center for Complementary and Alternative Medicine at NIH may offer more insight.

Based on the lack of reliable data at this time, RemiFemin or any other black cohosh product, is therefore not a safe recommendation for menopausal symptoms.

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MPhA Pharmacy News

March 2003

INSIDE

<i>Association News</i>	1
<i>Welcome New Members</i>	1
<i>MPhA Convention</i>	1
<i>Kelly Building</i>	1
<i>Around Maryland</i>	1
<i>Legislative Session</i>	1
<i>Methadone Program</i>	2
<i>News from School</i>	2
<i>Lab Exam Discontinued</i>	2
<i>NCPA Appointment</i>	2
<i>Other News</i>	2
<i>Medicare Card</i>	2
<i>HIPAA Compliance</i>	2
<i>Anti-Nerve Gas</i>	3
<i>Canadian Prescriptions</i>	3
<i>Open Networks</i>	3
<i>Senior Rx Help</i>	3
<i>OxyContin Replacement</i>	4
<i>Serevent Problems</i>	4
<i>Worth Reviewing</i>	4
<i>New Drugs, New Indications</i>	4
<i>Dietary/Herbal Supplements</i>	5
<i>FDA Seizures</i>	5
<i>Steroids</i>	5
<i>FTC Complaint</i>	5
<i>Post Scripts</i>	5



MPhA Pharmacy News is published monthly except during the months of March, June, September, and December, when the issues are combined with the "Maryland Pharmacist". For information about any article contained herein, contact MPhA at 410-727-0746 or 800-833-7587.

Web site: www.erols.com/mpha

President: Paul R. Holly, P.D.

Chairman: Mark Sanford, P.D.

Contributing Author: Melvin N. Rubin, P.D.

Editor: Howard R. Schiff, P.D.

Managing Editor: Elsie Prince

Association News

Welcome New Members

John F. McCarthy Jill Morgan

MPhA Convention

June 7 - 10, 2003 is the date for the MPhA 121st Annual Convention.

Reserve these dates and plan to attend the premier meeting of Maryland pharmacists.

The convention will be held at the Clarion

Resort Fontainebleau

Hotel in Ocean City,

Maryland. A full program of CEs and social events are planned. Watch for further details!



Kelly Building

The renovated lower level of the Kelly Building with the 1890s and 1950s pharmacies are beautifully displayed and provides a look back at Maryland pharmacy. It's a must see! Stop in and see for yourself.

Around Maryland

Legislative Session

The Maryland General Assembly is in full swing and MPhA is following a number of bills which affect pharmacists:

- SB 48 and HB 60 Controlled Dangerous Substances: Unfavorable report from Committee.
- SB 49 and HB 64 Forgery of CDS prescriptions or written orders: Unfavorable report from Committee.

Budget-Administration

Re: Medical Care Programs:

Following are possibilities given to legislature from DHMH-

- Increase discount on AWP from -10% to -12%
- Reduce pharmacy fee by 25 cents from current \$4.69 on brand and \$3.69 on generic
- Raise Medicaid copay by \$1.00
- Remove prohibition on MCO copay
- Supplemental rebates from preferred drug list (DHMH to institute per regulation shortly)
- Prior authorization on all brands when generic available

Hearings in House on 2/12 and Senate on 2/14.

HB615/SB354—Dispensing Emergency Contraception—

Excludes abortifacients but does not define drugs to be used—Hearings: House 3/6, Senate 3/13.

HB725—Senior Citizen Prescription

Relief Act—As a condition of participation in Medicaid, Medicare recipients receive Rx's at Medicaid price—Hearing: None set as of 2/18.

SB557—Health Coverage for All

Marylanders—Expansion of current programs to include all uninsured. Hearing: 3/13.

HB410—Examination of Pharmacy

Benefit Managers—Requires Insurance Commissioner to conduct examination of PBMs at least every three years—Hearing: 3/4.

HB363—Exclude Mental Health Drugs from Prior Authorization

under Medicaid—Would apply to preferred drug list—Hearing: 3/12.

HB208/SB376—Electronic Reimbursement by DHMH—Authorizing a pharmacy that submits electroni-

cally to DHMH to receive reimbursement electronically—Hearings: House 2/11, Senate 2/19.

HB548/SB537—Gifts from Pharmaceutical Manufacturers— Allows health occupation boards to discipline practitioners upon acceptance of gifts from pharmaceutical manufacturers valued at \$50 or more—Hearings: House 2/27, Senate 3/5.

Most of the above bills were still being heard for the first time at publication of this list. Since the Legislature moves fast at this time of the year, you can get up-to-date information on the text and status of the above bills by going to the Internet, at <http://mlis.state.md.us>, click on “bills status and information” and enter the bill initials and number.

Methadone Program

NIDA is working on the development of a model program for expanding methadone treatment from clinics to a more routine form of primary care.

A meeting was held at the School of Pharmacy with representatives of NIDA, DEA, Maryland Division of Drug Control, Office of Substance Abuse Studies, and the Maryland Board of Pharmacy.

The pilot project is expected to be done in New Mexico and in Baltimore and will involve pharmacies who will obtain a separate DEA number, and in Maryland, function as a University of Maryland Baltimore treatment program satellite dispensary. Pharmacists will be required to observe the dose being ingested and will have to provide consultation in a private area. Application forms are available on the Internet at www.deadi.version.usdoj.gov and can be sent to Dr. Tony Tommasello at the Office of Substance Abuse of the School of Pharmacy.

News from School

Dean David Knapp of the University of Maryland School of Pharmacy announced that the School has a section in a major exhibit devoted to the University of Maryland, Baltimore on display in the third floor atrium of the Miller Senate Office Building in Annapolis. The School has engaged a local media relations firm to develop and implement a marketing/communications plan. Four local TV stations were invited to film “b-roll” footage. This is file footage to be used as background on stories related to pharmacy. It is hoped that they will use the film from the practice lab, poison center and other locations rather than the traditional shots of pharmacists counting pills.

Lab Exam Discontinued

The Maryland Board of Pharmacy announced that the regulatory change has been finalized which will eliminate the Laboratory test as one of the requirements for licensure by examination in Maryland.

Candidates will be required to pay appropriate fees, pass the NAPLEX and Pharmacy Law Tests and show evidence of competency in oral English in order to be licensed in Maryland. The total fees will come to \$735 with \$600 of it going to the National Association of Boards of Pharmacy for the two national tests.

Graduates of foreign schools of pharmacy also have to apply through NABP for the FPGE examinations. The Reinstatement Regulations have been changed also, and will no longer require that a pharmacist whose license was expired for more than two years and is not actively practicing in another state to take the Laboratory test.

Reciprocity candidates had not been required to take that test.

NCPA Appointment

MPhA member William Popomaronis has been named director-pharmacy specialty services of the National Community Pharmacy Association.

His duties include responsibility for providing clinical, management, and reimbursement resources to independent pharmacists wishing to enter or currently specializing in the long-term care or home health care niche markets. “Bill” had been a co-founder and CEO of the Anchor Pharmacy group and previously was a co-founder and President of the EPIC independent pharmacy buying group.

Other News

Medicare Card

A Washington D.C. federal court Judge ruled that the Bush Administration’s Medicare-endorsed drug discount card initiative requires legislative authorization. The Centers for Medicaid and Medicare (CMS) said that they will work with Congress to clarify their authority while appealing the decision. The President is proposing \$400 billion in funding over 10 years for Medicare reform and prescription drug coverage, in the fiscal 2004 budget. AARP, however, feels that at least \$500 to \$600 billion is needed.

HIPAA Compliance

April 14 is the date that you must be compliant with the HIPAA privacy regulations. By now, most of the following should preparation have been done:

- HIPAA compliance Plan developed
- System for privacy of signatures in place (electronic or manual)
- Written policies and procedures in place
- Assurance that software companies have made appropriate arrangements for secure transmissions
- Notice of Privacy Practices printed
- Have personnel training material ready and training completed

- Plan to initiate monitoring of effectiveness of HIPAA compliance plan
- Be sure that your vendor is on track for the HIPAA administrative standards and transaction code sets—they must be in place now unless you have applied for an extension to October 16, 2003

Remember that HIPAA regulations apply to all pharmacies, no matter what size or what type of practice setting. Don't leave yourself exposed to disciplinary action and civil suits by ignoring the requirements or by not following through with them.

Anti-Nerve Gas

The FDA has approved a drug intended to increase the chance of survival for people exposed to the nerve gas, soman. The drug, pyridostigmine bromide (BP), is limited at this time to the U.S. military personnel. It has been successfully tested to animals. Given prior to exposure to the nerve gas soman, together with atropine and pralidoxine given after exposure, the therapy increased survival rates in the monkeys and guinea pigs used. FDA is allowed to accept animal data for proof of a drug's effectiveness when the drug can not be ethically or feasibly tested in humans. The drug was used experimentally during the Gulf War and was blamed by some troops for illnesses suffered after they returned home. The nerve agent, Soman, causes loss of muscle control and death from respiratory failure. Pyridostigmine bromide was originally approved to treat the neuromuscular disease myasthenia gravis.

Canadian Prescriptions

Although it is clearly illegal, except under certain limited conditions, to import prescription drugs from foreign countries, Canadian

pharmacies in particular are gearing up with more and more U.S. business. One estimate is that over a Billion dollars in medication is sent to the U.S. from Canada on an annual basis already. One Canadian town had about 40 pharmacies open within a few months, directing their marketing south. The weak Canadian dollar and government controls over prices make the Canadian offerings very tempting to Americans, particularly Senior Citizens. It has been reported that the Bethlehem Steel retirees who are losing their health insurance are being encouraged to use these pharmacies. Indications are that over a million Americans purchase drugs from Canada at this time. Attempts to stop the illegal practice is stymied as they are perceived as an attempt to make senior citizens pay more for medicine. This has caused many politicians to either support the practice or back off from attempting to stop it. GlaxoSmithKline announced that they would not sell their products to Canadian pharmacies who mail to the U.S. and had a back-lash from many areas including attempted boycotts of their products (AIDS Healthcare Foundation and others have called for boycotts). Adding to the problem is the difficulty in policing medications coming from Canada by mail. There has also been reports of shortages of drugs for Canadians with so many products being used to sell to the U.S. Despite the appearance of dramatic savings on all drugs, one study showed that generic drugs, on the whole cost 37% more from Canadian pharmacies than from American. A report from the Wharton School shows that an American who purchased all their drugs in Canada in 1992 would have saved a maximum of 13%.

Canadian VIPPS

The Canada National Association of Pharmacy Regulatory Authorities is planning to offer a Verified Internet Pharmacy Practice Site (VIPPS) program patterned after the National

Association of Boards of Pharmacy which offers what amounts to a seal of approval for Internet pharmacies. The Canadian group said that it will not make the seal available to any pharmacy which mails prescription drugs to U.S. residents.

Open Networks

A 2002 survey showed that employers favor open pharmacy networks to plans that restrict employees to a limited number of pharmacies. The survey also showed that there is little advantage to the employer to restricting their people to one or a few community pharmacies because the pharmacy professional fee has been shrinking even in open networks. The average dispensing fee for brand-name drugs in pharmacies participating in the survey dropped from \$2.50 in 1995 to \$2.31 in 2000 and just \$2.21 in 2001. 46% of employers reported that in 2001 they used a three tier copayment system—generic, preferred branded, non-preferred branded. Some are now using a fourth tier of cost sharing, adding a very high co-payment for lifestyle or selected high-cost drugs. Co-payments increased from 1999 to 2001 by over 20%, although co-payments for generic drugs had gone up only 8% in the survey.

Senior Rx Help

BenefitsCheckUpRx is a new service started by the National Council on the Aging, which will help Seniors with low incomes (under \$28,000 annual for single person, \$38,000 for married couple), find programs which will help them with the cost of prescription medication. There are at least 240 programs, covering nearly 800 drugs, to help people of various ages and income levels and this group will help them find the programs that will be of value to them. Go to www.benefitcheckup.org for information and help. The site also guides people with higher incomes to drug-discount cards

sponsored by drug companies and lists cards that are provided free to consumers and offer at least a 20% discount.

OxyContin Ads

The Food and Drug Administration issued an unusually stern warning to Purdue Pharma saying that the company "grossly overstated" the drug's safety in ads placed in the *Journal of the American Medical Association*. The ads do not say that OxyContin can cause fatal side effects nor does it discuss the potential for abuse, according to FDA. The advertisements also suggested broader use of OxyContin than is approved.

OxyContin Replacement

Purdue Pharma announced that they will replace any OxyContin (oxycodone HCL, controlled-release) tablets which are stolen from a pharmacy if the pharmacy is not insured for the loss. Requests for replacement for all uninsured OxyContin lost due to robberies from July 1, 2001 until the program is rescinded should be made in writing to Purdue Pharmacy along with documentation of the theft, including a complete written police report, a photocopy of DEA form 106, and a written certification that any of the pharmacy's insurance does not cover the loss. A Purdue spokesman said "Purdue does not wish to profit from criminal activity..."

Iressa Deaths

AstraZeneca reported that there are at least 173 deaths linked to its lung cancer drug Iressa, among the 473 patients who developed Lung disorders blamed on the drug in Japan. These numbers are from a population of 23,500 patients who were being treated with the drug for non-small-cell lung cancer. New rules were imposed in that country to restrict the use of Iressa to medical institutions capable of treating

patients with sudden side effects. These rules and other changes in the course of therapy has led to a decline in the rate of lung disorder side effects. AstraZeneca has applied to the U.S. FDA to review the information but the deadline has been pushed back to May.

Serevent Problems

Changes in the labeling of the package insert for Serevent (salmeterol, GlaxoSmithKline) are being considered based on reports that show an increased risk of asthma-related deaths in African-American patients and in patients not taking concomitant inhaled steroids. It is not yet known what difference the effects are when using Advair, which is GSK's combination inhalation therapy containing salmeterol and the inhaled corticosteroid in Flovent (fluticasone).

Worth Reviewing

MedWatch, the FDA Safety Information and Adverse Event Reporting Program is available on-line at <http://fda.gov/medwatch/Safety>. An example of the information available is the weekly posting of additions to the contraindications and/or warnings section. One week the additions included Aminosyn Products—contains aluminum that may be toxic; Larium—psychiatric symptoms; Renografin-60—severe adverse events—inadvertent intrathecal administration; Tequin—disturbances in blood glucose including symptomatic hyper- and hypoglycemia; Wellbutrin—contraindicated in patients undergoing abrupt discontinuation of alcohol or sedatives; and Zonegram—oligohidrosis and hyperthermia may be caused in pediatric patients. You can subscribe to the e-list at the MedWatch homepage, <http://www.fda.gov/medwatch>.

Attention K-Mart Pharmacists

If K-mart Corp receives the OK from the Court it will close 326 stores in an attempt to get out of Chapter 11 bankruptcy court protection by the end of April. This would result in the

closing of 259 pharmacies nationwide. A K-Mart spokesperson said that all pharmacists affected would be offered comparable jobs at other K-Mart stores.

British Market Rising

Eli Lilly and ICOS Corporation recently marked Cialis in Great Britain, as competition for Pfizer's erectile dysfunction drug Viagra. The product is said to take effect in 16 minutes and last up to 24 hours.

In the next few months Bayer and GlaxoSmithKline will jointly unveil Levitra, their version of an impotence pill, which they claim will be the most potent yet.

These products are currently not available in the U.S. because of court action by Pfizer blocking their entry in the marketplace. All three products work by blocking the same enzyme, PDE5, to increase blood flow to the penis.

New Drugs, New Indications

R Alinia (nitazoxanide) is available as an oral suspension for children for treating diarrhea caused by *Cryptosporidium* or *Giardia*, which are the common causes of persistent diarrhea. It appears as effective as metronidazole for *Giardia*, without significant adverse effects. Alinia is expected to be available later this year in a tablet form for adults and tests are underway to see if a higher dose and longer duration are effective for *Cryptosporidium* in patients with HIV.

R Amevive (alefacept, Biogen) has been approved to treat moderate to severe chronic plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.

R Avonex (Interferon beta-1a, Biogen) may now be used to treat patients with a first multiple sclerosis (MS) attack if brain MRI scan abnormalities characteristic of MS are shown.

R Cardizem LA (diltiazem HCL extended release, Biovail Corp) is a new formulation of diltiazem for the treatment of high blood pressure or hypertension. The product provides 24 hour blood pressure control with a single daily dose. With evening administration clinical trials have shown increased reduction in blood pressure in the early morning hours, which is when patients may be at the greatest risk of significant cardiac events.

R Humira (Adalimumab, Abbott) is a new therapy for rheumatoid arthritis with a tumor necrosis factor blocking agent similar to Remicade (infliximab) and Enbrel (etanercept). It can be used for moderate to severe rheumatoid arthritis (RA) that is not controlled by methotrexate or other disease-modifying antirheumatic drugs. Cost is about \$16,000 a year, usually given subcutaneously every other week.

R Lamactil (lamotrigine, GlaxoSmithKline) has been approved as an add-on therapy in partial seizures in patients age 2 years and up. This adds an available therapy for an age group for which there has been few options.

OTC Tavist ND (loratadine, Novartis) will be another competitor for Claritin. Novartis will be marketing their version both under the familiar name of Tavist and as private label store brands, both having retail prices "significantly less" than Claritin.

Dietary/Herbal Supplements

FDA Seizures

U.S. Marshals at the request of FDA seized dietary supplement products from Global Source Management and consulting Inc in Sunrise, Florida. Products include those sold under the names Vitamin Hut and RX for Health through retail booths and by mail order. Global Source has made claims of drugs that say they can

prevent various cancers and can treat arthritis.

Steroids

1-testosterone and 4-hydroxy-testosterone are being sold over the Internet and in some health food stores, being called "pro-steroids" or "legal steroids". They are only legal due to a technicality—not having been included in the original list of banned substances. They are ingredients in many brand name products such as 1-Test Ether, Androgen-1, TestXtreme, and Mag10, and carry the same risk as other anabolic steroids—hypertension, mood swings, liver damage, infertility, and cancer.

FTC Complaint

The Federal Trade Commission filed a complaint against Slim Down Solution and related companies for national ads run claiming that the product could absorb dietary fat and lead to weight loss without diet or exercise. The product, D-glucosamine, is a natural chemical in the body. Other names used for marketing the product include Fight the Fat, Everslim and Mini Max.

Post Scripts

□ A *Dermatology Online Journal* article tells of the overuse of high potency steroids such as Lotrisone in pediatrics for diaper rash or other problems. Their figures indicated that even experienced pediatricians do not realize that Lotrisone is a potent steroid and the problems it could cause with frequent use.

□ A survey showed that one of three Americans mistakenly believes antibiotics are effective in treating viruses like cold and flu and take this class of drugs to fight the conditions. This adds greatly to the problem of antibiotic sensitivity, and is the focus of an initiative entitled Save Antibiotic Strength New York (SASNY).

□ CVS settled with the attorney generals of several states related to billing practices concerning so-called

partial-fill prescriptions. CVS agreed to pay \$1.1 million to be divided among 18 states and the District of Columbia.

□ Federal Court documents showed that Medco Health Solutions favored Merck products despite their claims otherwise. Singulair accounted for nearly 76% of Medco's mail-order market for asthma drugs and Zocor commanded 41% of the cholesterol drug category in December 1999 although the overall national market share for Zocor was 22%. Medco offered \$42.5 million to settle the lawsuit.

□ A General Accounting Office study showed that federal employees paid about 50% less for generic drugs through their managed care plans than they did if purchased retail in pharmacies. The difference on brand name was about 18%. The study has been challenged by some pharmacy groups.

□ Thalidomide plus dexamethasone may become the treatment of choice for myeloma patients with low tumor mass, according to an article in the *Journal of Clinical Oncology*.

□ This is a reminder to be careful with Depakote ER and Depakote prescriptions. The extended release product now comes in a 250mg and 500mg tablet and is approved for preventing both migraines and seizures. It is a once daily product, compared to the original Depakote having a BID or TID dose. The Depakote ER gives a lower blood level, so they are not bioequivalent.

□ Arava (leflunomide) apparently can increase warfarin's effects. The INR can increase significantly in just a few days.



God Bless America

Drotrecogin Alfa (Xigris) in Treatment of Severe Sepsis

By Dong Oh, Pharm. D. Candidate

Sepsis is defined as systemic inflammatory response to infection. A systemic inflammatory and procoagulant response to infection may result in sepsis and it occurs when patients fit two or more SIRS (Systemic Inflammatory Response Syndrome) criteria and has a proved or presumed infection.^{1,2} Sepsis can then lead to severe sepsis where it is associated with organ dysfunction, hypoperfusion, or hypotension. Sepsis can also be associated with severe hypotension despite adequate fluid resuscitation along with the presence of perfusion abnormalities, which is called septic shock.² Given these definitions, it has been reported that about 750,000 patients in U.S. become severely septic every year with mortality rate of 30% despite proper care.¹ It remains the most common cause of death among ICU patients and cost associated with treating severe sepsis in United States is about \$17 billion per year.²

Available treatments

It used to be that attention was focused on inflammation as the dominant process of sepsis cascade but many of the proposed anti-inflammatory therapies failed and a search for the new therapy was undertaken. The need for alternative therapy other than antibacterial was necessary because although antibacterial drugs were essential in treating sepsis, it was not sufficient for the treatment of severe sepsis. It was during these investigation that Eli Lilly developed drotrecogin alfa (Xigris) through the understanding that disease process is caused by a loss of homeostasis between inflammation, coagulation, and fibrinolysis.^{3,4} Drotrecogin alfa is a recombinant form of human activated protein C.⁵ It is a glycoprotein analog of native protein C synthesized and secreted by genetically engineered human cells, which was found to be present in subnormal levels in patients with sepsis.^{4,6} A deficiency of protein C is associated with increase morbidity and mortality and patients with severe sepsis can become rapidly depleted in endogenous protein C.¹ The action of protein C is to inhibit coagulation, increase fibrinolysis and also shown to inhibit synthesis of tumor necrosis factor in vitro.⁶ Drotrecogin alfa acts in a similar manner as endogenous activated protein C. It slows down the coagulation process in the microvasculature by

proteolytic inhibition of coagulation factor Va and VIIIa.¹ It also reduces inflammation by indirectly inhibiting thrombin mediated inflammatory activities and fibrinolysis is enhanced by inhibiting thrombin production.¹ For the activation of protein C, the binding of endogenous protein C to thrombomodulin and endothelial protein C receptor is required but in severe sepsis, the conversion of protein C to activated protein C may be impaired.¹

Adverse effects

The major toxicity of drotrecogin alfa was found to be serious bleeding. In clinical trial, PROWESS study, a randomized, double-blind, placebo-controlled, and multi-center trial, it was reported that 3.5% of the treated patients out of 850 treated patients compared to 2.0% out of 840 patients in placebo group.⁷ The only difference in the incidence of serious bleeding between the two groups was observed during the infusion period and the incidences thereafter was similar in the two groups. Serious bleeding includes fatal hemorrhages, GI, and intra-abdominal bleeding were most common and the most serious bleedings occurred only during the infusion.⁶ It was reported that there are to be no other safety concerns associated with drotrecogin alfa use on the basis of assessment of organ dysfunction, vital signs, serum chemical data, or hematologic data.⁷

Cost

One of the draw back of using drotrecogin alfa is that it costs about \$6,800 per therapeutic course which is usually continuous intravenous infusion for 96 hours at rate of 24 mcg/kg/hr.⁸ Efficacy of drotrecogin alfa was at an absolute reduction in the risk of death of 6.1% according to PROWESS study and its recommended use is limited to patients with APACHE II (Acute Physiology and Chronic Health Evaluation II) above 25.⁸ Limitation is that APACHE II score is often not utilized by many institutions and is more often very subjective depending on the person evaluating. Therefore, deciding who receives the drotrecogin alfa therapy and who doesn't becomes controversial.

Conclusion

There is new hope for the patients with severe sepsis. There is additional therapy available to them with promising efficacy associated with it. With currently available information out there today, the faith of patients with severe sepsis is in the hands of physician who determines the use of drotrecogin alfa.

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AND THE LAW

Don McGuire, R.Ph., J.D.

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“WHY WORRY ABOUT TORT REFORM?”

In November 2002, there was a television news magazine program reporting on a pharmacy in a small town in Mississippi that is sued almost weekly because it had dispensed prescription drugs that have since been withdrawn from the market. Products liability cases have been a large legal problem facing pharmacists and pharmacies since the withdrawal of phenfluramine and Redux. This type of case also followed the withdrawal of Duract, Rezulin, Propulsid, and Baycol.¹

The deluge of lawsuits in Mississippi has focused the national media's attention on the state. The press has examined the tort system (torts are the area of the law that includes negligence) in Mississippi and its negative effects on pharmacy, medicine, hospitals, and many other types of small businesses. The intense pressure of public opinion caused the Mississippi legislature to pass, and the governor to sign, a tort reform bill. What does tort reform mean to pharmacists? Why is it important to pharmacists in every state?

All litigation proceeds under a set of rules established by statute, regulation, and/or court rules. The intent of procedural rules is to establish a level playing field for both plaintiffs and defendants. Changes in

society over time can cause this balance to shift in favor of one side or the other. Shifts in recent years in favor of plaintiffs has caused an abundance of suits and judgments. Tort reform is necessary to restore the balance in the system.

One way Mississippi is trying to restore this balance is by addressing the question of joint and several liability. Under pure joint and several liability, the plaintiff is entitled to recover the entire judgment for one, or all, of the defendants. Current law in Mississippi allows someone who is found to be only 1% at fault to pay 50% of the judgment. This encourages plaintiffs to not settle out with minor parties because of the potential that the minor party will be forced to pay more than their share. The new law provides for several liability only, for non-economic damages. This means a party 1% at fault will pay only 1% of the non-economic damages (for example, pain and suffering). For economic damages (for example, lost wages or medical expenses), a party 30% or less at fault will pay only their own percentage. A party more than 30% at fault could pay up to 50% of the economic damages. The implication for defendants is that a minor player will not be forced to pay a lion's share of a judgment.

¹ Products liability law was discussed more fully in a previous article in this series.

For products liability cases in particular, the new law will allow an innocent seller (such as pharmacies selling OTC phenylpropanolamine products) to be dismissed from a lawsuit where the manufacturer is also sued. This will be a tremendous boon to pharmacies that have been named in suits in an attempt to keep those cases in state courts. This has been a particular problem in those cases involving withdrawn drugs. The new law provides that the manufacturer will stay in state court. Additionally, the time for an innocent seller to give notice to the manufacturer for indemnification will increase from 30 days from the date that the lawsuit is filed to 90 days from the date that the suit is served upon the innocent seller. This will give pharmacies more time to tender cases to the manufacturers where they are innocent sellers of the products.

The new Mississippi law also places a cap on punitive damages. Punitive damages are awarded in more wanton or reckless cases of negligence and are intended to punish the wrongdoer. Punitive damages will be limited to as little as 4% of the net worth of a defendant whose net worth is \$50 million or less, up to \$20 million for a defendant with a net worth more than \$1 billion. It is worth noting that the cap is not applicable in cases of a felony or when negligent action was made under the influence of alcohol or illegal drugs. This

cap will eliminate some of the huge jury verdicts that have been reported in the last few years. These huge verdicts, of course, fuel the tort system.

The new law in Mississippi also addresses other topics such as judge shopping, hedonic damages, out of state lawyer advertising, and frivolous lawsuits. The net effect of these changes is that the tort system in Mississippi will not be as favorable to plaintiffs as it has been in the past. Alabama also enacted tort reform as a response to some huge jury verdicts and punitive damage awards in that state. Pharmacists should contact their state legislators if tort reform is on their state's legislative agenda because support from constituents is vital to passage of tort reform. Proposals for tort reform meet stiff opposition from the plaintiff bar and your voice needs to be heard for bills, such as the Mississippi reform, to get passed.

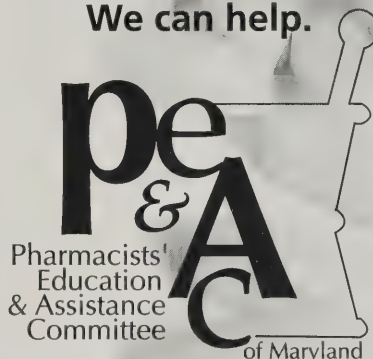
© Don McGuire, R.Ph., J.D., is a Professional Liability Claims Attorney at Pharmacists Mutual Insurance Company.

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with the policies and procedures of their employers and insurance companies, and act accordingly.

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Continuing Education for Pharmacists

Volume XX, No. 10

Patient Counseling: Xyrem in the Treatment of Narcolepsy

Thomas A. Gossel, R.Ph., Ph.D.
Professor Emeritus
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph.,
Pharm.D.
Professor Emeritus
University of Cincinnati
Cincinnati, Ohio

Goals: The goal of this lesson is to discuss narcolepsy and the use of sodium oxybate (Xyrem) in management of cataplexy, a prominent symptom.

Objectives: At the conclusion of this lesson, successful participants should be able to:

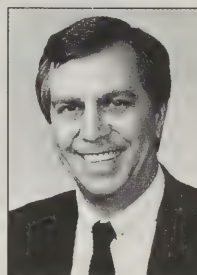
1. recognize key features of narcolepsy and cataplexy;
2. exhibit knowledge of the pharmacologic and therapeutic considerations for use of Xyrem (sodium oxybate) in management of cataplexy;
3. identify adverse effects and major toxicities associated with the use of Xyrem; and
4. demonstrate an understanding of how to counsel patients on

*This lesson is provided by an
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narcolepsy and cataplexy, and the medical use of Xyrem.

Approximately 125,000 people in the U.S. suffer from narcolepsy, a disorder characterized by intermittent, uncontrollable episodes of falling asleep during the daytime.

Over the years, narcolepsy has been treated subjectively with CNS stimulants. FDA has recently approved a new drug, Xyrem (sodium oxybate), whose action is aimed at treatment of cataplexy, one of the predominant symptoms of narcolepsy. Sodium oxybate is the salt of gamma-hydroxybutyrate (GHB), a compound that was once banned from use in the U.S. because of its potential for abuse and serious toxicity with instances of coma and death.

Narcolepsy

The onset of narcolepsy occurs generally in the second or third decades of life. However, both the young and the elderly may experience inappropriate sleep attacks. Narcolepsy affects both genders equally. Whether narcolepsy is a chronic disorder that persists over a lifetime remains controversial.

Narcolepsy is an idiopathic (without known cause) disorder of the CNS that is defined classically as the tetrad of uncontrollable

episodes of daytime somnolence (sleepiness), cataplexy (short, intermittent periods of muscle weakness), hypnagogic and hypnopompic hallucinations (hallucinations while falling asleep or upon waking), and sleep paralysis (paralysis while falling asleep or upon waking). In reality, the full tetrad is rare. Most affected patients experience inappropriate sleepiness, with or without cataplexy. The sleep attacks are nearly irresistible, most often persist less than 30 minutes, may be associated with dreaming, and promote a refreshed feeling upon awakening. Excessive daytime sleepiness often occurs earlier in life with the other symptoms appearing several years later.

Three percent of narcoleptic patients have a first-degree relative with the disorder. A genetic linkage has been identified. Approximately 90 to 100 percent of narcoleptic sufferers with cataplexy have the genetic markers, as opposed to fewer than 50 percent of non-narcoleptic individuals. Although these findings are inconclusive, they suggest that immune system studies with focus on identifying a genetic link will define a large portion of the scientific investigation of narcolepsy in the future. In fact, it has been postulated that all patients with a true endogenous sleep disorder exhibit a genetic component to their symptoms.

Patients with narcolepsy experience inappropriate intrusions of rapid eye movement (REM) sleep. In patients with normal sleep-wake patterns, REM sleep usually occurs approximately 90 minutes after sleep onset. Investigations reveal that 50 percent of patients with narcolepsy experienced REM sleep

Table 1
Prevalence of Symptoms in Narcolepsy

Symptom	Prevalence (%)
excessive daytime somnolence	100
disturbed sleep	87
cataplexy	76
hypnagogic hallucinations	68
sleep paralysis	64
memory problems	50

modified from Roth TA, Merlotti L. *Narcolepsy 3rd International Symposium, Selected Symposium Proceedings*, Chicago, Matrix Communications, 1989

onset within the first 10 minutes of sleep. The result is believed to disrupt the natural sleep cycle, and promote myoclonic movements with less time spent in deep sleep. The initial cause may be due to a general change in the individual's bio-rhythm associated with narcolepsy.

Cataplexy. Cataplexy is the most prevalent and certainly the predominant secondary symptom of narcolepsy. It is almost exclusive to narcolepsy, occurring in approximately three out of four narcoleptic patients (Table 1). Cataplexy is defined as a sudden, temporary loss of muscle tone (i.e., transient paralysis) in the body.

The severity of attacks varies, as patients may experience two or three attacks per day, per year, or even per decade. When loss of muscle tone is severe, all the voluntary muscles are affected, leading to complete collapse. In milder cases of cataplexy, loss of muscle tone can be subtle, involving only a few muscle groups. For example, partial weakness in the muscles of the jaw may result in transient sagging of the jaw lasting only a few seconds. Or, weakness in the neck muscles may cause the individual to struggle to keep his head upright. Eye muscles are not affected during a cataplectic episode. The individual remains completely conscious during an attack and later will usually be able to recall the entire event. It is nearly impossible to bring an individual out of an

episode. Cataplectic attacks normally last from a few seconds to up to 30 minutes; rarely do they last longer.

Cataplectic attacks are believed to be related to intense emotional situations, such as extreme anger, escorting a daughter to the altar in marriage, or roaring laughter. This distinguishes cataplexy from narcolepsy, the onset of which does not correlate with the patient's emotional state.

Diagnosis

Confirmation of narcolepsy is established by clinical recognition of excessive daytime somnolence with uncontrollable sleep, the presence of cataplexy (although, as stated earlier, this occurs in only three out of four patients), and the absence of normal causes of excessive daytime sleepiness. The presence of hypnagogic and hypnopompic hallucinations and/or sleep paralysis suggests narcolepsy; however, they are not exclusive to the condition in that they may occur in non-narcoleptic patients.

The symptoms of narcolepsy seem distinct to the disorder, but they warrant differential diagnosis. Excessive daytime sleepiness, for example, may also be indicative of serious pathology, such as brain tumor or anemia. Uncontrollable sleep in response to these conditions is usually more extensive, lasts longer, and does not allow the patient to feel refreshed.

Affective disorders, including depression, may share symptoms such as tiredness and disrupted sleep with narcolepsy. These conditions often respond to REM sleep manipulations. Distinguishing between narcolepsy and these other conditions may require comprehensive lifestyle assessment.

Treatment

There is no cure for narcolepsy. It is treated symptomatically and consists of both nonpharmacologic and pharmacologic interventions. This includes getting sufficient nocturnal sleep, observing proper sleep hygiene

practice, and drug therapy. Proper sleep hygiene, including a consistent sleep schedule and the avoidance of shift work and alcohol, is of primary importance.

Patients with narcolepsy often feel refreshed after a short nap. Short, scheduled naps may, therefore, benefit patients by combating excessive daytime sleepiness. If the patient's daily schedule will permit, a 15 to 20-minute "power nap" after lunch and a second one preceding or following dinner may help reduce the intensity of daytime sleepiness and magnify temporary alertness.

Pharmacologic. Central stimulants have been the mainstay of drug therapy for somnolence and daytime sleep attacks in narcolepsy patients. Stimulants include methylphenidate, dextroamphetamine, modafinil, and pemoline. Dosages are determined on an individual patient basis, and are generally taken in the morning and at noon.

Tricyclic antidepressants including imipramine, nortriptyline, and protriptyline are commonly prescribed for cataplexy; selective serotonin reuptake inhibitors, such as fluoxetine, work especially well in treating cataplexy; and selegiline often improves the condition. The common mechanism in all three classes of drugs for treating cataplexy may be in their action to suppress REM sleep. Cataplexy is often much worse in sleep-deprived patients who have poor sleep hygiene. Establishing good sleep practices may be the most significant factor in controlling this symptom.

Sodium Oxybate (Xyrem)

Xyrem is a potent psychoactive drug that produces a wide variety of pharmacologic activities including a potent depressant effect on the CNS. It has recently been approved for treatment of cataplexy in patients with narcolepsy.

Mechanism of Action. "The precise mechanism by which Xyrem produces an effect on cataplexy is unknown." A nondescriptive statement, perhaps, but this is the exact

wording of the drug's mechanism of action as stated in the product's package insert.

Pharmacokinetics. Xyrem is rapidly but incompletely absorbed following oral administration; absorption is delayed and decreased by a high-fat meal. The average time to peak plasma drug concentration ranges from 0.5 to 1.25 hours. Xyrem is eliminated mainly by biotransformation with a half-life of 0.5 to one hour. Pharmacokinetics are nonlinear with blood levels increasing 3.7-fold as the dose is doubled from 4.5 to 9gm. The pharmacokinetics are not altered with repeated dosing.

Clinical Experience. The effectiveness of Xyrem in treating cataplexy in patients with narcolepsy was established in two randomized, double-blind, placebo-controlled parallel group trials (Trials 1 and 2). It was the outcome of these trials that led to FDA's approval of Xyrem as a legitimate drug. In each trial, the treatment duration was four weeks. The total daily doses ranged from 3 to 9gm, divided into two equal doses. The first dose each night was taken at bedtime, with the second dose taken 2.5 to four hours later. About 85 percent of the patients in both trials were also being treated with CNS stimulants.

Trial 1 enrolled 136 patients with narcolepsy who had moderate to severe cataplexy. Group members had a median of 21 cataplectic attacks per week at baseline. Prior to randomization, all medications with possible effects on cataplexy were withdrawn, but stimulants were continued at stable doses. Patients were randomized to receive placebo, or sodium oxybate at doses of 3gm/day, 6gm/day, or 9gm/day.

Trial 2 employed a similar protocol except that it was a randomized withdrawal study. It enrolled 55 narcoleptic patients who had been taking open-label sodium oxybate for seven to 44 months. To be included, patients needed to have a history of at least five cataplectic attacks per week prior to any

treatment for cataplexy. Patients were randomized to continued treatment with sodium oxybate at their stable dose or to placebo. The second trial was designed specifically to evaluate the continued efficacy of sodium oxybate after long-term use.

In Trial 1, statistically significant reductions of -10 and -16 in the frequency of cataplectic attacks per week were recorded for patients taking either 6gm/day or 9gm/day doses. The 3gm/day dose had little effect. In Trial 2, following the discontinuation of long-term open-label sodium oxybate therapy, patients randomized to placebo experienced a significant increase in the number of cataplectic attacks, providing evidence of long-term efficacy of treatment. In Trial 2, the response was numerically similar for patients treated with doses of 6gm/day or 9gm/day.

Adverse Effects. A total of 448 patients with narcolepsy were given Xyrem in clinical trials. The most commonly reported adverse events associated with the use of the drug are shown in Table 2. Two deaths were noted, both from drug overdoses. In these trials, 13 percent of patients discontinued treatment because of adverse events.

The drug's professional label contains a black box warning to apprise of its strong potential for abuse and toxicity including coma and death. The abuse of Xyrem can lead to dependence, craving to acquire the drug, and withdrawal symptoms when it is discontinued. Xyrem is contraindicated in patients being treated with sedative-hypnotic agents.

Indications and Uses. Xyrem is indicated for the treatment of cataplexy in patients with narcolepsy.

Availability and Dosage. Xyrem must only be taken at bedtime while the patient is in bed. One measured dose and 60mL of water are placed in each of the two 90mL dosing cups provided with the product. The patient takes the first dose at bedtime and should be awakened 2.5 to four hours later for

Table 2
Adverse Effects Associated with Xyrem*

Response	% of Patients Reporting Event
headache	25
nausea	21
dizziness	17
pain	16
somnolence	13
pharyngitis	11
infection	10
viral infection	10
flu syndrome	9
accidental injury	9
diarrhea	8
urinary incontinence	8
vomiting	8
rhinitis	8
muscle weakness	8

*responses reported by 8 percent or more of 448 narcoleptic patients in clinical trial

the second dose.

The recommended daily starting dose is 4.5gm divided into two equal doses of 2.25gm. The dosage can be increased in increments of 1.5gm/day (0.75gm/dose) to a maximum of 9gm/day. Two weeks between dosage increases are recommended to evaluate clinical response and minimize adverse effects. The efficacy and safety of Xyrem at doses higher than 9gm/day have not been investigated, and doses greater than 9gm/day ordinarily should not be administered.

As noted earlier, food significantly reduces drug absorption. Therefore, patients should not eat within several hours of going to sleep. They should also maintain a similar schedule, if possible, between timing of meals and Xyrem administration. Xyrem is supplied as a clear to slightly opalescent oral solution. It is provided in kits containing one bottle of Xyrem, a press-in-bottle-adaptor, a 10mL oral measuring device, a Medication Guide, a professional insert, and two 90mL dosing cups with child resistant caps. The bottle contains 180mL of Xyrem at a concentration of 500mg/mL. No more than a three-month

Table 3
Resources for Narcolepsy and its Medical Management

Orphan Medical, Inc.
877.679.9736
www.orphan.com

American Academy of Sleep Medicine
507.287.6006
www.aasmnet.org

National Organization for Rare Disorders, Inc.
800.999.6673
www.rarediseases.org

National Sleep Foundation
202.347.3471
www.sleepfoundation.org

Narcolepsy Network
513.891.3522
www.narcolepsynetwork.org

Talk About Sleep
901.482.2025
www.talkaboutslee.com

supply of Xyrem can be shipped to any patient at one time.

Xyrem has been placed in a dual-level Federal Schedule. For legitimate medical use, it is classified as a Schedule III controlled substance. For illegitimate use, the active ingredient, sodium oxybate (i.e., gamma-hydroxybutyrate), is listed in Schedule I, the most restrictive schedule of the Controlled Substances Act, which is reserved for non-medical uses of drugs and chemicals. This means that anyone who gives Xyrem to anyone else or who uses Xyrem in a manner other than prescribed, is liable for punishment under state and federal laws. First-time offenders could be sentenced up to five years in prison and also fined up to \$250,000. A second offense could result in 30 years imprisonment and a fine of up to \$2 million, or confinement for life if the recipient is seriously injured by the drug.

An Historical Perspective on Gamma-hydroxybutyrate (GHB)

Gamma-hydroxybutyrate was developed originally as an anesthetic

and later withdrawn from commerce because of unwanted side effects. In the early-1990s, GHB was promoted as a popular dietary supplement. Proponents of its use cited its ability to induce sleep, release growth hormone, enhance sexual activity and athletic performance, and relieve depression. The drug gained favor for recreational use, especially among young adults. Its rapid onset of sedation, coupled with its amnesic features and rapid and complete clearance from the body, increased its illicit use for date rape.

Many reports of serious adverse events, including numerous deaths, were linked to the use and misuse of GHB. As its use increased, so did the reports of adverse events. That prompted FDA to publish several public service announcements to alert consumers of the dangers of GHB. While GHB-containing products were listed on Internet sites as "party drugs," and advertised and promoted in body-building magazines and health food stores as dietary supplements, FDA considered them to be unapproved new drugs. As a result of the increasing number of serious adverse events including death, FDA seized the products to prevent their sale to consumers to curtail further illnesses or deaths.

Since that time, however, Orphan Medical Inc. conducted the required scientific studies to establish GHB's usefulness in reducing the number of cataplectic attacks in patients with narcolepsy. FDA granted priority review status to the new drug application and, when the clinical trials were completed, approved it as an Orphan Drug. Orphan Drug status is available for products that are intended to treat disorders with patient populations of 200,000 or fewer. Sponsors receive special economic incentives including a seven-year exclusivity for marketing, tax credit toward the cost of product-associated clinical trials, and assistance from FDA in research design.

The Xyrem Success Program

The Xyrem Success Program is designed to ensure safe use of the drug. Under the program, because of safety concerns associated with its use, Xyrem is available through a single centralized pharmacy. The program incorporates numerous risk management components, such as required physician and patient education, registration to prescribe the drug, and detailed patient surveillance. The Xyrem Success Program includes detailed information about the safe and prudent use of the medication, as well as information to help the patient prevent accidental use or abuse of Xyrem by others.

Xyrem will be shipped directly to the patient once it is documented that the patient has read all educational materials. Alternatively, patients or their insurance company may request that the prescription be sent to a community pharmacy for patient pick-up. This affords pharmacists an excellent opportunity to become even more involved in patient care. Pharmacists are urged to obtain a copy of the Xyrem Medication Guide, available at: www.fda.gov/cder/drug/infopage/xyrem/medicationguide.htm, or by calling 1-877-67-XYREM (1-877-679-9736). Table 3 includes references to contact for additional information on narcolepsy and its medical management.

Continuing Education Quiz

This month's questions are taken from the article on "Patient Counseling: Xyrem in the Treatment of Narcolepsy." Circle your answers to the following questions and mail the entire page to Maryland Pharmacist CE, 650 W. Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members \$ 10.00). The completed quiz for this issue must be received by 10/15/05. A continuing education certificate for one and one-half contact hours (0.15 CEUs) will be mailed to you within six to eight weeks. Please type or print clearly. ACPE# 129-144-02-010-H01.

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1. The common name for the substance of abuse that was previously removed from commerce, but is now the active ingredient in Xyrem is:

- a. LSD.
- b. GHB.
- c. ludes.
- d. speed.

2. When a condition such as narcolepsy is without known cause, it is referred to as being:

- a. congenital.
- b. hereditary.
- c. idiopathic.
- d. nosocomial.

3. Cataplexy is defined as:

- a. a sudden, temporary loss of muscle tone.
- b. difficulty sleeping due to lack of air when breathing.
- c. uncontrollable muscle movements in the legs at night.
- d. hypersensitivity to cat dander.

4. Which of the following statements about a cataleptic attack is true?

- a. Muscles in both the legs and the eyes are affected.
- b. Patients nearly always lose consciousness during their episodes.
- c. Patients rarely remember what happened to them during the attack.
- d. It is nearly impossible to bring an individual out of an episode.

5. The mainstay of drug therapy for somnolence and daytime sleep attacks in narcolepsy has been with:

- a. antipsychotics.
- b. barbiturates.
- c. central stimulants.
- d. opioids.

6. Xyrem is best described as having which of the following activities?

- a. Central depressant
- b. Central stimulant
- c. Peripheral depressant
- d. Peripheral stimulant

7. The black box warning in the professional labeling for Xyrem refers to its potential for:

- a. affecting cytochrome P-450 enzyme activity.
- b. causing cancer in laboratory animals.
- c. abuse and toxicity including coma and death.
- d. causing liver damage in susceptible patients.

8. The correct dosage regimen for Xyrem is to take it:

- a. with lunch at noontime, followed by a dose after supper.
- b. at bedtime while in bed, and again 2.5 to four hours later.
- c. in the morning, 30 minutes before ingesting any food or liquid.
- d. four times a day with meals and at bedtime with a snack.

9. All of the following statements about Xyrem are true EXCEPT:

- a. food significantly reduces drug absorption.
- b. patients should maintain a similar schedule for timing meals and Xyrem administration.
- c. a Medication Guide is provided with the product.
- d. it is supplied as a chewable tablet which must not be swallowed whole.

10. Although the active ingredient in Xyrem is listed in Schedule I, when used for legitimate medical use Xyrem is classified as:

- a. Schedule II.
- b. Schedule III.
- c. Schedule IV.
- d. Schedule V.

CORRECTION: The correct ACPE number for Patient Counseling: Management of Sore Throat which appeared in the Jan./Feb./Mar. 2002 issue of the Maryland Pharmacist is 129-144-01-011-H01.

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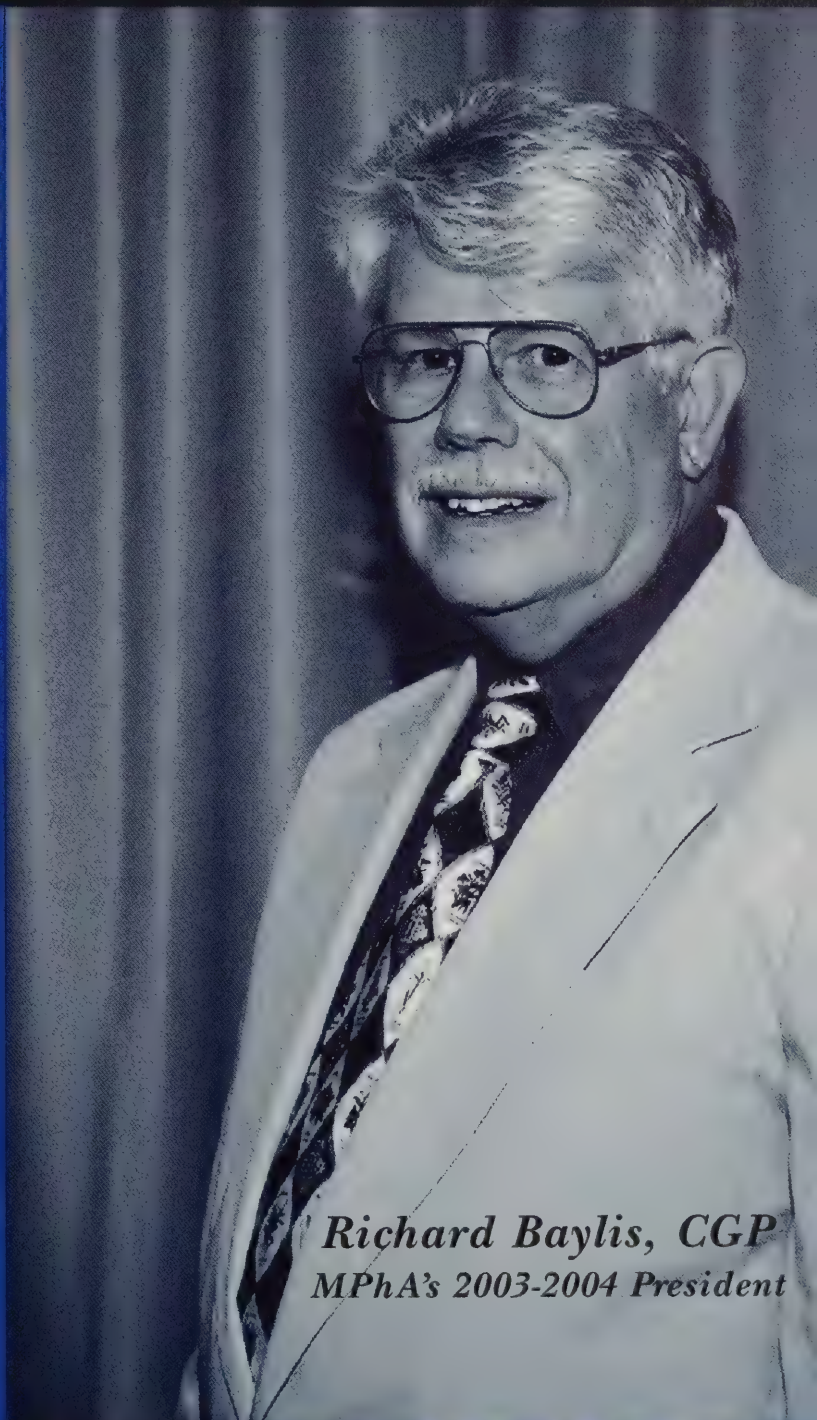
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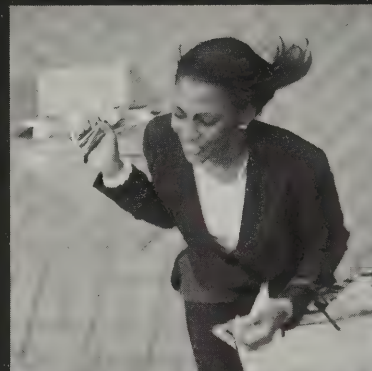
President's Address	5
Director's Column	7
RX and the Law	9
121st Annual Convention Photos	12
Continuing Education	18
Patient Counseling: " Management of Strep Throat"	

Advertiser's Index

Mayer & Steinberg	16
McKesson	11
Medicine Shoppe	6
PEAC	17
Pharmacists Mutual	8
RPh on the go	4
Shreddit	17
Walgreens	24

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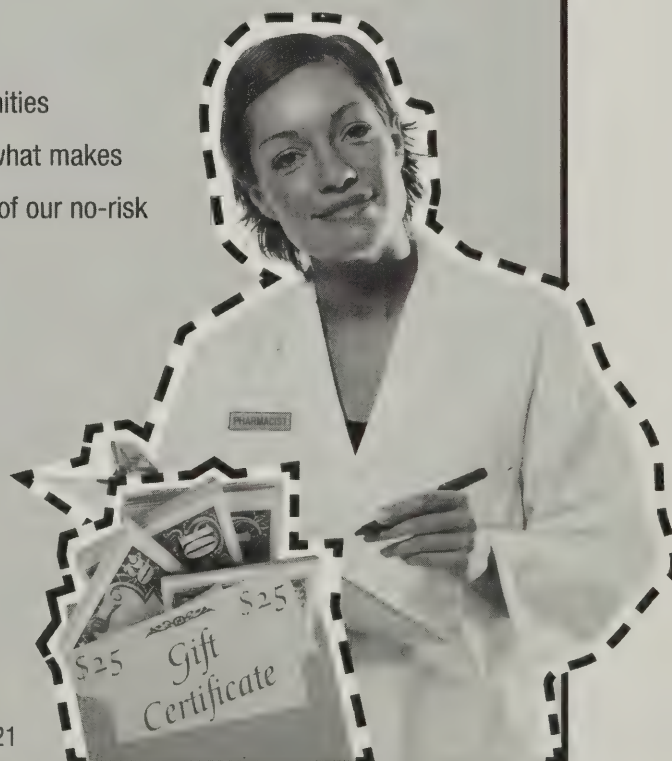
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President's Address

I am honored to be elected by my fellow colleagues as the 119th president of the MPhA. I have been active in the affairs of MPhA for many years including working as DUR Director in MPhA's office.

The association has worked hard to represent all facets of our profession. We are ever mindful of the rapid changes taking place in practice sites. The association must continue to reexamine its goals and objectives to reflect these changes as they occur.

Over the last few years we have expended a tremendous amount of energy in strengthening the association by encouraging membership, participation in association functions, lobbying our legislature and publicizing our profession via the media.

The association has reached out to our fellow pharmacy organizations in the state and was instrumental in forming the Maryland Pharmacy Coalition. Now our professional societies are working together to present a positive public image.

We are often asked by potential members...what does the MPhA do for me?

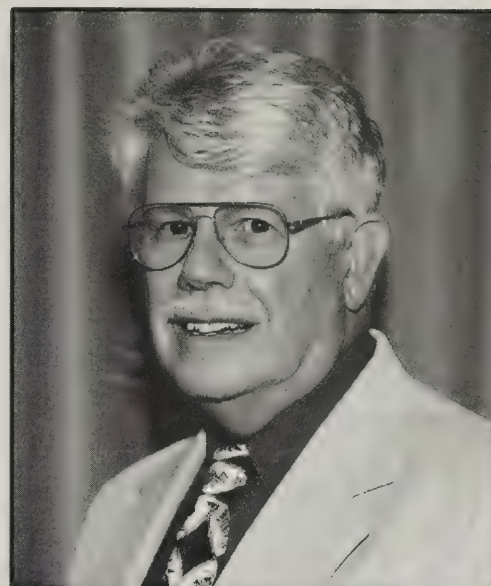
First we publish a newsletter and journal. We have a web site that keeps us all posted as to our many activities. The executive director and legislative chairperson monitor legislative and regulatory activity over the entire year. They marshal our forces when issues need to be addressed. They inform the membership of all these activities in a prompt manner to elicit response to the issue at hand. In cooperation with our fellow associations, through MPC, we troop down to Annapolis and let our voices be heard. Our Director attends most of the Board of Pharmacy meetings in order to present our side of issues brought before the Board. He and members also testify before legislative committees to present our position on a particular issue.

Many pharmacists do not call the Board of Pharmacy about regulations...they call MPhA. Do you know why? Because we have compiled, added a commentary, edited

and printed a pharmacy lawbook entitled "*Laws and Regulations for the State of Maryland*", we can answer their questions.

Over the years we have challenged reimbursement changes attempted by CareFirst BlueCross BlueShield, Maryland Medicaid, Maryland Pharmacy Assistance, Baltimore City employee health benefits, federal upper limits schedules, pharmacy school funding (supporting expansion and opposing budget cuts), and even our own Board of Pharmacy actions.

We have also served on various task forces and committees to review and revise pharmacy laws and regulations. We actively promoted the passage of the Drug Therapy Management Bill in the state legislature. Our members now serve on the committee advising the Board of Pharmacy in writing the regulations to implement this ground breaking law.



**Richard Baylis, CGP
President**

Our executive director advocates our members' appointment to any pharmacy related task force or committee.

The Bioterrorism Response Task Force has two of our members serving on it. They were there before September 11. Eight hundred of Maryland's pharmacists have volunteered to serve when needed for such an emergency.

The association has become very conscious of our need to be favorably presented in the public eye. Last fall, with the cooperation of the MPC, a banner was designed and placed across Light Street marking National Pharmacy Week. Last week we appeared on Channel 13's "Coffee With" showing off the renovated lower section of the B. Olive Cole Museum. We are also posted on their web site at WJZ.com.

The renovations of the Kelly Memorial Building are forging ahead. Over the last three years or so, we have replaced the roof, windows and painted the exterior of the building. This last winter we rebuilt the two pharmacies we have as part of the B. Olive Cole Pharmacy Museum. The next step is to renovate and fix up the main floor offices and museum areas. This will take around another \$100,000.

The final goal of fund raising is to raise around 1.5 to 2 million dollars to form a Foundation Fund to provide pharmacy scholarships to Maryland residents and continue the maintenance and upkeep of the Kelly Memorial Building and B. Olive Cole Pharmacy Museum.

How did we do all this? We had the strong backing of VOLUNTEERS! That's how an association builds its strength and character. Volunteerism makes the wheels go round and projects get accomplished. Through our volunteer efforts we have influenced legislators, bureaucrats and increased public awareness of whom and what we are.

We can do more. We have a serious problem of increased medication errors. This has been attributed to many factors—one of which is the tremendous increase in prescription volume and the lack of personnel to fill them safely. If the association is to represent ALL pharmacists, then we must assist those pharmacists in coping with the enormous work load. Working conditions—

especially if they are going to affect our accuracy and integrity as a health profession—need to be addressed by us as a professional society along with the employers of these pharmacists.

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Generally, the spring National Community Pharmacists Association (NCPA) legislative conference is a call for advocacy on specific bills favorable to the independent pharmacy community. This year was different. The conference focused on the alleged abuses of Pharmacy Benefit Managers (PBMs). Although, the Medicare prescription drug benefit had not been introduced as of this writing, there is no doubt that the administration's plan promises to make extensive use of PBMs.

Dr. Bob Garis, pharmacist and Ph.D. from Creighton University, spoke at the conference. He's doing research on PBMs and the AWP (defined by Garis as Ain't What's Paid) spread with PBM mail order pharmacies. He has found a spread of more than \$10 per RX for some employers. Allegedly some mail order pharmacies owned by PBMs are repacking generics, assigning new NDCs and higher AWP, promoting them with higher discounts to payers and charging those payers more than what would be charged by the community pharmacy. The belief is the PBMs are using multiple AWP as well as multiple Maximum Allowable Costs (MACs).

Allegedly, PBMs switch patients to higher priced medications in order to get larger rebates from manufacturers then don't pass on those rebates to the payer and cause pharmacies to stock unnecessary inventory. James G. Sheehan, Associate United States Attorney for the Philadelphia area and another speaker at the conference, has taken action against at least one PBM alleging favoritism for one manufacturer to the detriment of payers and patients. He further claimed that rebates were listed as "value added services" enabling the manufacturer to avoid creating a new best price for



Howard Schiff
Executive Director

government programs. PBMs have refused to reveal to Congress rebates received from manufacturers, calling that information proprietary.

Perhaps the worst of the allegations constitutes outright fraud. The adjudicated net cost of a prescription, after discount and copay, paid to a pharmacy is increased when presented to a payer. Under the veil of privacy, privilege and proprietary information, this allegation has shown to be hard to prove.

No one denies that PBMs are well qualified to be administrators. It's when corporate greed and the desire to look good for the quarterly report takes over that PBMs run afoul of good sense. Hopefully, the public and the government will realize that pharmacist's standing as the most trusted professional will prevail and fairness will return to the prescription market place.



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AND THE LAW

By Karen E. Peterson, R.Ph., J.D.

This series, **Pharmacy and the Law**, is presented by Pharmacists Mutual Insurance Company and your State Pharmacy Association through Pharmacy Marketing Group, Inc. a company dedicated to providing quality products and services to the pharmacy community.

PHARMACISTS' EXPANDED SCOPE OF DUTY: IT HAS ITS ADVANTAGES

It is logical for pharmacists to expect that as their scope of duty expands, their potential exposure to liability will increase. This is evident in recent court cases that have held pharmacists liable, even when filling a prescription exactly as it was written.¹ While this increased risk of liability can be somewhat daunting, it is a relatively small price to pay for the advantages that accompany the higher standards to which pharmacists are being held.

A recent case in Michigan demonstrates one of the advantages that accompany the expanded scope of duty.² The facts are simple. In December of 1998, the plaintiff had a prescription filled. She was given the wrong medication, took it for several days, and experienced a host of side effects, including a rash on her body, a high fever, hearing loss, hallucinations, and crying spells. She brought suit against the pharmacy several years later, alleging that the pharmacy was negligent for filling her prescription incorrectly, hiring incompetent employees, and failing to properly train and supervise employees.

Some background is necessary to understand what happened next. In many states, including Michigan, there are special rules for bringing medical malpractice lawsuits. Michigan requires a plaintiff to notify a potential medical malpractice defendant of the intent to sue six months in advance of actually filing suit. In addition, Michigan requires a plaintiff to file documentation signed by a health care professional

stating that the claim actually has merit. Finally, the statute of limitations for medical malpractice claims in Michigan is shorter than that for other tort claims. These special rules exist as an effort to protect health care professionals and entities from frivolous lawsuits.

The plaintiff in our lawsuit did not follow these special rules. She claimed she did not have to because she was alleging ordinary negligence, not medical malpractice. The trial court dismissed the case because of the plaintiff's failure to follow the procedures for filing a medical malpractice lawsuit. The plaintiff appealed the dismissal, again arguing that she was not claiming medical malpractice, but rather ordinary negligence.

The court correctly identified that "the core issue in this case is whether plaintiff's complaint alleges medical malpractice...or ordinary negligence."³ In its analysis of the issue, the court stated, "the key to a medical malpractice claim is whether it is alleged that the negligence occurred within the course of a professional relationship."⁴ In addition, the court cited a previous case which offered further clarification on the difference between medical malpractice and ordinary negligence:

The determination whether a claim will be held to the standards of proof and procedural requirements of a medical malpractice claim as opposed to an ordinary negligence claim depends on whether the

facts allegedly raise issues that are within the common knowledge and experience of the jury or, alternatively, raise questions involving medical judgment⁵.

This means that a claim will be considered medical malpractice if: (1) the alleged negligence occurred within the course of a professional relationship; and (2) the facts of the case involve questions of medical judgment. The court concluded that the allegations in our plaintiff's complaint met both of those criteria. They reached this decision because they determined that a pharmacy is considered a health care provider for the purposes of Michigan's malpractice statutes. As such, the alleged negligent dispensing of a prescription occurred within the course of the pharmacy's professional relationship with the plaintiff. Additionally, "because the issues in this case involve dispensing prescriptions, they raise questions involving medical judgment."⁶

What does this mean to our plaintiff's case? It was dismissed. She failed to follow the requirements for filing a medical malpractice lawsuit within the timeframe for doing so and her negligence claim, although timely, was not appropriate. This means that this plaintiff is completely barred from bringing a lawsuit against the pharmacy for her incorrectly filled prescription.

This case is important to pharmacies and pharmacists. The result is correct, even if it may not seem fair from the patient's perspective. There did not seem to be any dispute that the prescription was filled incorrectly, yet because of a technicality, the patient was not compensated for her injuries. The importance of the case is that it demonstrates the difference between negligence and medical malpractice. Additionally, this case highlights the fact that although an expanded scope of duty subjects pharmacists to greater liability exposure, the expanded scope of duty also means that pharmacists may be protected from frivolous lawsuits in the same manner as physicians and other health care professionals.

© Karen E. Peterson, R.Ph., J.D., is a Professional Liability Claims Attorney at Pharmacists Mutual Insurance Company

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with the policies and procedures of their employers and insurance companies, and act accordingly.

¹ Happel v. Wal-Mart Stores, Inc., 199 Ill.2d 179. Pharmacy was held liable for failure of duty to warn patient that NSAID prescribed for her was contraindicated.

² Graham v. Rite Aid Corp., 2003 WL 21079858 (Mich. App.).

³ Id.

⁴ Id.

⁵ Dorris v. Detroit Osteopathic Hosp. Corp., 460 Mich. 26, 46 (1999).

⁶ Graham, *supra* at 2.

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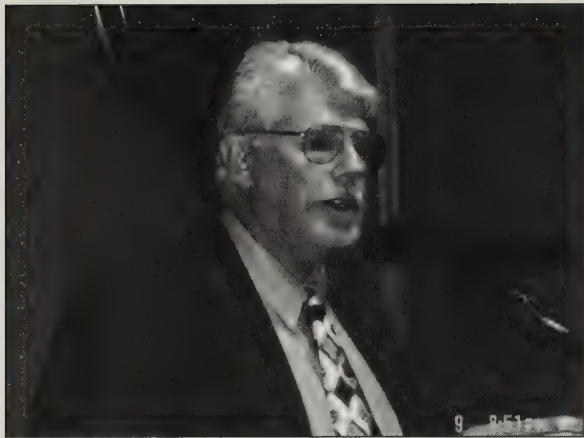
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Diphenhydramine

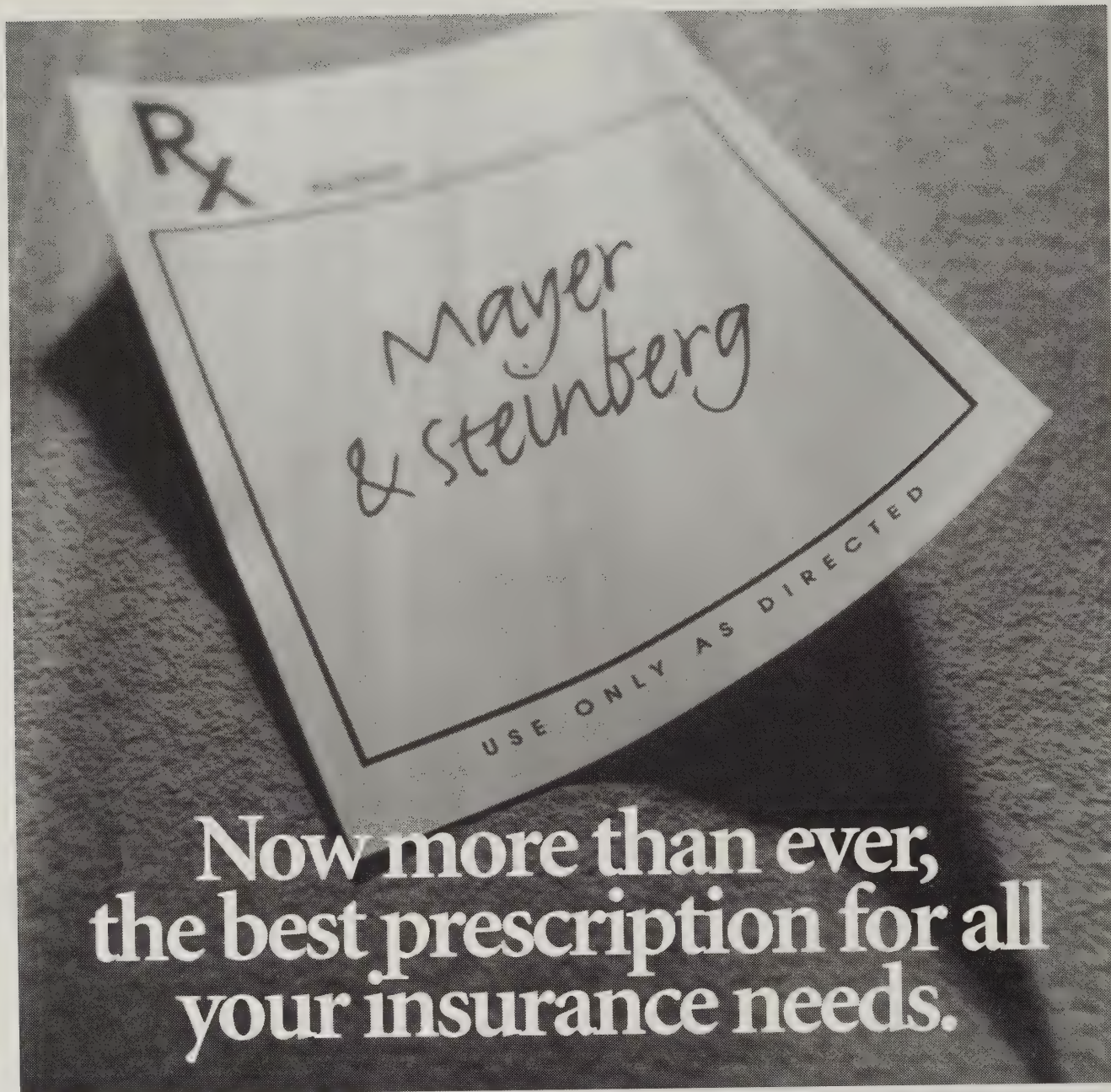
Diphenhydramine is an antihistamine commonly found in over-the-counter products as an antitussive, a nighttime sleep-aid, or to relieve allergy symptoms. It is also used for chemotherapy-induced nausea and vomiting, drug-induced extrapyramidal reactions, motion sickness, anaphylaxis and urticaria. In 2002, the Maryland Poison Center was consulted on over 500 exposures to diphenhydramine products in children and adults. Overdoses occur as a result of unintentional ingestions by small children, intentional overdoses by teens and adults, and abuse by teens and young adults.

Serious symptoms in adults may be seen with ingestions of greater than 1 gram. Children are more sensitive to the toxic effects with seizures having been reported with doses as little as 150 mg to 200 mg. Fatalities in children have been reported with less than 500 mg. The fatal dose in adults is estimated to be 20-40 mg/kg.

The most common clinical effects seen with large doses of diphenhydramine are a result of its anticholinergic properties. Neurological symptoms predominate and may progress from agitation, drowsiness and confusion to hallucinations, seizures and coma. Other anticholinergic symptoms that patients will present with include dry and warm skin, flushing, tachycardia, hypertension, hyperthermia, dilated pupils and urinary retention. Massive ingestions of diphenhydramine have been associated with a widening of the QRS interval due to sodium channel blocking properties, similar to what is seen in tricyclic antidepressant overdoses.

Initial treatment of diphenhydramine overdoses consists of gastrointestinal decontamination with activated charcoal. Although absorption of diphenhydramine is usually rapid (within one hour), activated charcoal may be of benefit even several hours after ingestion because of decreased GI motility. Sodium bicarbonate has been effective in treating the cardiac conduction abnormalities. Benzodiazepines are used to treat anticholinergic delirium and seizures. For additional information on the treatment of diphenhydramine overdoses, call the Maryland Poison Center 1-800-222-1222.

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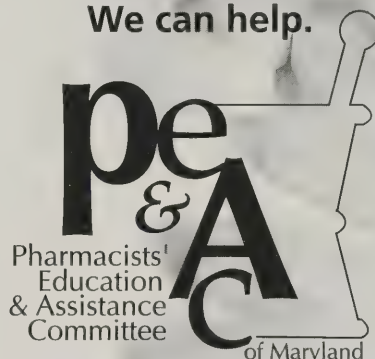
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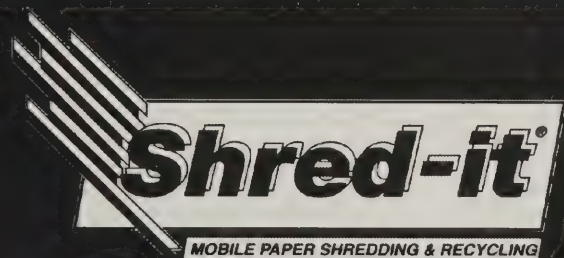
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Continuing Education for Pharmacists

Volume XX, No. 11

Patient Counseling: Management of Strep Throat

Thomas A. Gossel, R.Ph., Ph.D.
Professor Emeritus
Ohio Northern University
Ada, Ohio

and

**J. Richard Wuest, R.Ph.,
Pharm.D.**
Professor Emeritus
University of Cincinnati
Cincinnati, Ohio

Goals. The goals of this lesson are to discuss strep throat including its cause, significance, and treatment, and provide information for pharmacists to use when counseling patients.

Objectives. At the conclusion of this lesson, successful participants should be able to:

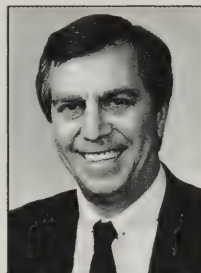
1. exhibit knowledge of the pathogenesis and etiology of strep throat;
2. differentiate between sore throat conditions caused by bacterial and non-bacterial pathogens;
3. exhibit knowledge of information on current drugs used to treat strep throat; and
4. demonstrate an understanding of how to counsel patients with strep throat.

*This lesson is provided by an
educational grant from*

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Wuest

More than 65 percent of cases of pharyngitis (inflamed, painful throat) are reported to be idiopathic (no known cause). Group A beta-hemolytic streptococcus (hereafter referred to as streptococcus) is the most common cause of acute bacterial pharyngitis (streptococcal pharyngitis; strep throat). It accounts for 15 to 30 percent of cases in children and 5 to 10 percent of cases in adults. The infection occurs primarily in children age five to 15 years, with a second peak in incidence between ages 30 and 39 years. Strep throat usually appears in winter and early spring. Signs and symptoms of streptococcal and non-streptococcal pharyngitis overlap considerably, so accurate diagnosis is important.

Clinical Features

Certain epidemiological and clinical features of acute streptococcal pharyngitis are characteristic for the infecting microbe. Signs and symptoms include sore throat (generally of sudden onset in adolescents and adults but more gradual in children), pain on swallowing, and fever. Fever is moderate with periodic chills. Headache, nausea, vomiting, and abdominal pain may also be present, especially in children. Strep throat is classically associated with weakness and mild neck stiffness.

The tonsils and surrounding surfaces will appear extremely red with or without exudates. The anterior cervical lymph nodes will be enlarged (lymphadenitis). Other signs may include a dark-red and swollen uvula (the fleshy mass that hangs down from the back of the throat), petechiae (tiny clots) on the palate, excoriated nares (especially in infants), and a bright rash.

Although these findings appear in strep throat in 35 to 50 percent of patients, none is specific for streptococcus. They may occur with non-bacterial (viral) upper respiratory infections as well. Of note is the presence of conjunctivitis, cough, hoarseness, coryza (runny nose), inflammation in the back of the mouth, discrete ulcerative lesions in the mouth, or diarrhea which strongly suggest a viral rather than streptococcal infection. Table 1 summarizes clinical features of pharyngitis that help differentiate between bacterial and non-bacterial infections.

Differentiating Bacterial and Non-bacterial Causes

The most common non-bacterial causes of acute pharyngitis are viruses. Respiratory viruses including adenovirus, parainfluenza virus, rhinovirus, and respiratory syncytial virus are frequent causes. Others include coxsackievirus and ECHO viruses as well as herpes simplex virus. Epstein-Barr virus is a frequent cause, often accompanied by additional clinical features of infectious mononucleosis (e.g., swollen lymph nodes and enlarged spleen). Systemic infection with cytomegalovirus, influenza virus, measles virus, rubella virus, and other viral agents may be associated

Table 1
Clinical and Epidemiological
Features Useful in Diagnosis
of Pharyngitis

Suggestive of streptococcus

Sudden onset of throat pain
Pain on swallowing
Fever ($>101^{\circ}\text{F}$)
Headache
Nausea, vomiting, abdominal pain
Inflammation of pharynx and tonsils
Patchy discrete exudates
Tender, enlarged lymph nodes in neck
Patient age 5 to 15 years
Presentation in winter or early spring
History of exposure

Suggestive of viral etiology

Conjunctivitis
Runny nose
Cough
Diarrhea
Hoarseness
Sores (lesions) in the mouth

with acute pharyngitis. Other microbials such as *Mycoplasma pneumoniae*, *Neisseria gonorrhoeae*, *Arcanobacterium haemolyticus*, and *Chlamydia pneumoniae* are rare causes of acute pharyngitis. In addition to the group A beta-hemolytic streptococcus, other bacteria are also capable of producing acute throat inflammation and pain resembling strep throat. These include group C and group G beta-hemolytic streptococci and *Corynebacterium diphtheriae*.

Streptococcus may be spread by direct person-to-person contact through nasal secretions or saliva. Outbreaks are common in areas of communal living such as military and college dormitories, and in schools and family dwellings. Outbreaks resulting from human contamination of food during preparation have also been reported. Although anecdotes are numerous and a few cases have been reported, family pets are rare carriers of streptococcus.

The organism may colonize in throats without causing symptoms. Individuals can be carriers of the infection. Small children often have symptoms too mild for diagnosis.

The physician generally considers the clinical findings before ordering laboratory testing. A history of intimate contact with a person who has a well-documented case of streptococcal pharyngitis will be helpful in determining a probable cause. Testing is normally unnecessary for patients whose clinical and epidemiological features suggest a non-streptococcal infection.

The Tests

Throat Cultures. The standard means to document the presence of streptococcus is to culture a throat swab on a sheep blood agar plate. A single throat swab has a specificity of 99 percent, with a sensitivity of 90 to 95 percent in correctly identifying the presence of streptococcus. The disadvantage of throat cultures is that the delay (overnight or longer) in identifying the organism may result in delaying the start of therapy.

Rapid Antigen Detection

Tests. To overcome diagnosis and treatment delays from the traditional throat cultures, rapid antigen detection tests (RADTs; rapid strep tests) have been developed. The tests detect the presence of streptococcal carbohydrate on a throat swab, and may be performed in the physician's office. Although they are more expensive than blood agar cultures, these tests offer advantages in obtaining more speedy test results and therapy initiation, reduction in the risk of disease spread, and less time off the job.

The RADTs currently available have a specificity of 95 percent or higher than blood agar plate cultures. Their sensitivity is between 80 and 90 percent (lower in some reports) when compared with the blood agar plate cultures. It is recommended that a negative RADT result should be confirmed with conventional blood agar plate culture results. Both the American Academy of Pediatrics and the American Heart Association endorse obtaining a positive RADT result before initiating treatment with antibiotics. Newer tests (optical immunoas-

say and a gene probe test) with increased sensitivity are being developed.

Management of Strep Throat Infections

The goals of therapy for strep throat are to:

- prevent suppurative and non-suppurative complications (Table 2);
- abate clinical symptoms and signs;
- reduce bacterial transmission to close contacts;
- permit the rapid resumption of usual activities; and
- minimize potential adverse effects of antimicrobial therapy.

Suppurative (pus forming) complications of strep throat occur as infection spreads from the pharyngeal mucosa to deeper tissues. Streptococcus can also cause severe, invasive infections. Rarely, the infection may lead to meningitis, pneumonia, or bacteremia.

The major non-suppurative complication is acute rheumatic fever. Poststreptococcal glomerulonephritis is another. Rheumatic fever occurs more often in children with streptococcal pharyngitis than in adults with this bacterial infection. It presents as a diverse syndrome of clinical manifestations making diagnosis difficult. Onset of symptoms of rheumatic fever occurs within several days to five weeks after a strep throat infection. A patient with rheumatic fever will have a fever (101° to 104°F), and painful swelling of several joints such as the knees, elbows, or wrists. Severe rheumatic fever attacks can damage heart valves.

Antibiotic Therapy

Antibiotic therapy is indicated for individuals with pharyngitis whose tests are positive for streptococcus. Failure to treat streptococcal throat infection can result in various suppurative and non-suppurative complications as stated above and listed in Table 2. Treatment of pharyngitis of viral or non-bacterial irritants with antibiotics is useless. Therefore, proper management of acute pharyngitis is directed prima-

Table 2
Complications of
Streptococcal Pharyngitis

Non-suppurative Complications
Rheumatic fever
Poststreptococcal glomerulonephritis
Suppurative Complications
Cervical lymphadenitis
Sinusitis
Mastoiditis
Otitis media
Meningitis
Bacteremia
Endocarditis
Pneumonia

rily at identifying patients with true strep throat who require antibiotic therapy, as well as avoiding unnecessary and inappropriate treatment in patients with acute viral pharyngitis.

Important issues to consider when selecting an antibiotic for treatment of group A beta-hemolytic streptococcal pharyngitis include:

- bacteriologic and clinical efficacy;
- patient allergies;
- compliance issues;
- frequency of administration;
- palatability;
- cost;
- spectrum of activity; and
- potential adverse reactions.

Choice of Antibiotic. Many antibiotics have been shown to be effective for treating streptococcal throat infections. These include penicillin and its congeners (e.g., amoxicillin), numerous cephalosporins, macrolides, and in certain cases, clindamycin.

Penicillin. Penicillin has been the drug of choice for treating strep throat infection for more than 50 years because of its proven efficacy, safety, narrow spectrum of activity, and low cost. From the early 1950s into the 1970s, strep throat was treated with a single intramuscular injection of penicillin G benzathine. Published studies from the late-1960s and the 1970s showed that the extent of streptococcal eradication was the same with intramuscularly and orally administered penicillins.

Oral penicillin VK has been the preferred treatment since the early-1980s.

Penicillin therapy has some disadvantages. Some patients may be allergic to it; allergy is more common in adults than children. Allergic reactions are more frequent following injection than with oral ingestion. Compliance with a four-times-daily dosing schedule is difficult for some patients. Fortunately, efficacy in strep throat infection is reported to be similar for 250mg doses of penicillin VK when it is taken two, three or four times daily.

Amoxicillin. The cure rates in children receiving amoxicillin once daily for 10 days are equivalent to those for penicillin VK. Food does not hinder absorption of amoxicillin, and the drug's serum half-life is longer in children than that of penicillin VK.

Amoxicillin is relatively inexpensive and has a narrower spectrum of antimicrobial activity than some of the newer drugs. Chewable tablets are available. Gastrointestinal side effects and skin rash may be reported more commonly with amoxicillin than penicillin VK.

Amoxicillin-Clavulanate Potassium. This combination drug product (e.g., Augmentin) is resistant to degradation from beta-lactamase enzymes. Amoxicillin-clavulanate potassium is frequently recommended to treat recurrent strep throat. Diarrhea is its major adverse effect.

Macrolides. Erythromycin is a first-line alternative in patients who are allergic to penicillin derivatives. However, reports state that 15 to 20 percent of patients cannot tolerate adverse gastrointestinal effects of erythromycin.

Azithromycin. A once daily dose of Azithromycin (Zithromax) for five days is approved as second-line therapy for treatment of strep throat in persons 16 years of age and older. The drug has a lower incidence of gastrointestinal side effects than erythromycin. However, its effectiveness in preventing acute rheumatic

fever has not been substantiated.

Cephalosporins. A 10-day course of therapy with a cephalosporin antibiotic has been shown to be more effective than penicillin (92 percent versus 84 percent for penicillin) in eradicating streptococcus. Cephalosporins have an extended spectrum of activity over penicillin VK. First-generation agents such as cefadroxil and cephalexin are preferred to the broader-spectrum second- or third-generation agents.

Some penicillin-allergic persons are also allergic to cephalosporins. Patients with immediate hypersensitivity (i.e., anaphylactic-type) to penicillin should not receive a cephalosporin.

Unless prescribed otherwise, antibiotics should be administered for 10 days to achieve maximal eradication of streptococcus. Selected oral cephalosporin agents have been administered in shorter courses with reported bacteriologic and clinical cure rates that are comparable to penicillin administered for 10 days. Only the azithromycin five-day course currently has FDA approval.

Resistance to antibiotics has not been a significant issue to-date in the treatment of streptococcal pharyngitis in the U.S. In fact, an authenticated report of group A streptococcus resistance to penicillin could not be found in the literature. There are geographic areas where isolates with resistance to macrolide antibiotics (specifically erythromycin) have been reported, but this has not been a clinically significant problem to-date in North America.

Approximately one-fourth of individuals in close contact with a patient with strep throat may have a positive culture, but remain asymptomatic. It is usually not necessary to treat them if they are asymptomatic. When a large group (e.g., individuals in school, daycare centers, dormitories) is involved, throat cultures (or RADTs) should be performed on all patients. Only those with positive results should be treated with antibiotics.

Occasionally, patients will suffer

Table 3
Patient Information:
Streptococcal Pharyngitis
(Strep Throat)

- Your antibiotic has been prescribed for five to 10 days of therapy. Be sure to take the entire amount prescribed even if symptoms go away after the first few days. Do not skip doses.
- Your sore throat may persist even after an antibiotic has effectively treated the infection. You may gargle with a warm salt-water solution, or use an OTC product to help relieve the pain. Your doctor or pharmacist can recommend an effective product.
- Other treatments may also help relieve pain of strep throat. These include:
 - Drink a mixture of tea, lemon and honey.
 - Drink cold liquids or eat frozen desserts.
 - Avoid citrus products such as orange juice which may add to the discomfort.
 - Ask your doctor or pharmacist to recommend an appropriate product to control pain and fever.
- Patients with strep throat are considered contagious until they have been taking an antibiotic for 24 hours. During that time, do not return to school or work, and avoid close contact with other people. Wash your hands thoroughly, often, and use a handkerchief when you cough or sneeze.
- The bacterium that causes strep throat can persist on your toothbrush and orthodontic appliances (false teeth, retainers, etc.) for up to 15 days. Be sure to rinse your toothbrush thoroughly after each use and your appliances thoroughly after removing them from your mouth.
- If your child has strep throat:
 - Call the doctor at once if the child starts drooling, has great difficulty swallowing, or is acting very sick.
 - Call the doctor during office hours if the child has a fever that lasts over 48 hours after starting to take an antibiotic.

antibiotic therapy. A single episode may be treated as before. When episodes occur repeatedly over the course of months or years, the infection may be controlled adequately with oral amoxicillin/clavulanate or penicillin G benzathine.

Over the past 50 years, numerous antibiotic agents have been examined in clinical trials and shown to be effective in eradicating streptococcus from the upper respiratory tract. It should be recognized, however, that the only antibiotic that has been thoroughly examined in controlled studies and found to prevent initial attacks of rheumatic fever is intramuscular long-acting penicillin. Penicillin G benzathine is effective in primary prevention of rheumatic fever (prevention of an initial attack of rheumatic fever following an episode of strep throat). It is also proven effective in preventing rheumatic fever in patients who have had a previous attack of the disease (secondary prophylaxis). While other antibiotics can eradicate streptococcus from the upper respiratory tract, the evidence remains inconclusive that such eradication is effective in the prevention of rheumatic fever.

Advising Patients

As with all antibiotics, compliance is extremely important. Patients should be told they must take their medicine for the full course of therapy even if they feel better, unless their physician tells them to stop earlier.

An increase in bowel movements when taking antibiotics is not uncommon. If severe diarrhea occurs, patients should check with their physician before self-treating with OTC antidiarrheal products.

For penicillin VK, amoxicillin and most cephalosporins, the dose can be taken with or without food. Manufacturers of amoxicillin/clavulanate state that the dose should be taken with food.

Erythromycin base is destroyed by stomach acid, and therefore should be taken on an empty

stomach. However, the delayed release forms (formerly referred to as *enteric-coated*) protect erythromycin from destruction in the stomach and can be taken with or without food.

There are no restrictions on taking Zithromax with food or on an empty stomach, but the manufacturer does warn that antacids containing aluminum or magnesium salts should not be taken within two hours of the dose.

Nonprescription analgesics are helpful in alleviating the sore throat, headache and fever associated with strep throat. Because of the potential for Reye's syndrome, aspirin should not be used in children and teenagers unless directed by a physician.

Additional information to use in counseling patients on strep throat is provided in Table 3.

Overview

Strep throat is a bacterial infection of the pharynx caused primarily by group A beta-hemolytic streptococcus that requires antibiotic treatment. Penicillin VK (orally) or penicillin G benzathine (intramuscularly) are antibiotics of choice. Treatment can prevent serious complications such as rheumatic fever or glomerulonephritis. In addition, with treatment, the fever and much of the sore throat pain are usually gone within 24 hours.

recurrences of acute pharyngitis and harbor positive cultures for group A streptococcus within a short period following completion of a course of

Continuing Education Quiz

This month's questions are taken from the article on "Patient Counseling: Management of Strep Throat." Circle your answers to the following questions and mail the entire page to Maryland Pharmacist CE, 650 W. Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members \$ 10.00). The completed quiz for this issue must be received by 11/15/05. A continuing education certificate for one and one-half contact hours (0.15 CEUs) will be mailed to you within six to eight weeks. Please type or print clearly. ACPE# 129-144-02-011-H01.

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1. The most common cause of acute bacterial pharyngitis is which of the following subgroups of streptococcus?

- a. Group A beta-hemolytic
- b. Group C beta-hemolytic
- c. Group E beta-hemolytic
- d. Group G beta-hemolytic

2. The fleshy mass that hangs down from the back of the throat is the:

- a. adenoids.
- b. epiglottis.
- c. palate.
- d. uvula.

3. Which of the following viruses is most likely to cause pharyngitis accompanied by mononucleosis?

- a. Adenovirus
- b. Epstein-Barr
- c. Influenza
- d. Rhinovirus

4. Which of the following clinical features of pharyngitis is most suggestive that the infection is streptococcal rather than viral?

- a. Conjunctivitis
- b. Diarrhea
- c. Fever
- d. Runny nose

5. Both the American Academy of Pediatrics and the American Heart Association endorse finding a positive result on which of the following tests before initiating antibiotic therapy in patients with sore throat?

- a. Gene probe test
- b. Liver function test
- c. Optical immunoassay
- d. Rapid antigen detection test

6. The term "suppurative" refers to:

- a. bleeding sores.
- b. fever producing.
- c. pus forming.
- d. tiny clots.

7. All of the following are suppurative complications of streptococcal pharyngitis EXCEPT:

- a. otitis media.
- b. rheumatic fever.
- c. pneumonia.
- d. meningitis.

8. Which of the following is a first-line alternative for patients who are allergic to penicillin?

- a. Erythromycin
- b. Cephalexin
- c. Azithromycin
- d. Amoxicillin-Clavulanate

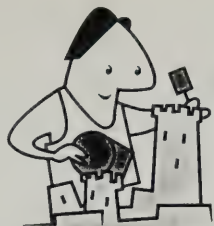
9. Patients with strep throat are considered contagious until they have been taking an antibiotic for:

- a. 24 hours.
- b. 72 hours.
- c. seven days.
- d. 10 days.

10. Parents of children with strep throat should be advised to call the doctor at once if the child exhibits any of the following symptoms EXCEPT:

- a. acting very sick.
- b. developing a fever.
- c. having great difficulty swallowing.
- d. starting to drool.

CORRECTION: The correct ACPE number for Patient Counseling: Management of Sore Throat which appeared in the Jan./Feb./Mar. 2002 issue of the Maryland Pharmacist is 129-144-01-011-H01.



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President's Address

Preceptors Needed... 5

Director's Column 7

Ban on Importation?

New Guidelines

Controlling and Treating Blood Pressure 9

Membership Benefits and Investment Form 11

Prilosec OTC 16

IRS News Release

Over-the-Counter Drugs to be Covered by Health Care Flexible Spending Accounts 17

Continuing Education 18

Patient Counseling: "Alzheimer's Disease: Part 1: The Disease"

Advertiser's Index

Advocate RX	4
Mayer & Steinberg	15
McKesson	24
PEAC	4
Pharmacists Mutual	6
Shreddit	8

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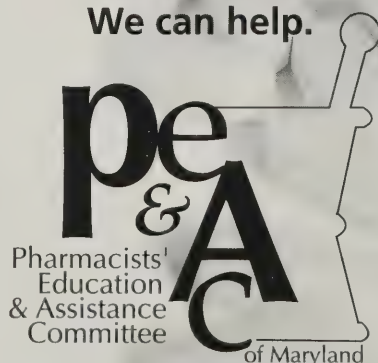
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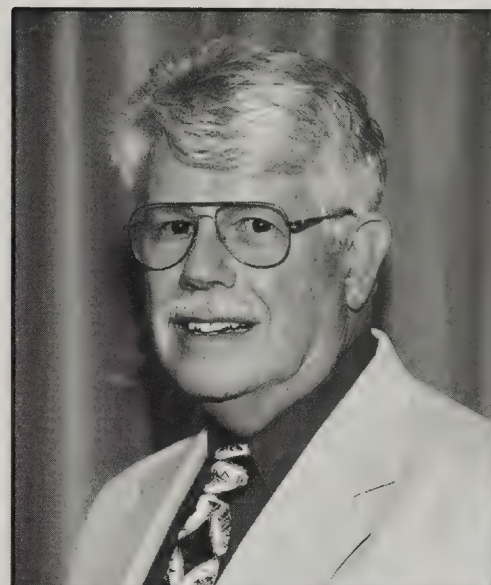
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President's Commentary

Preceptors Needed...

Historically, aspirants to become pharmacists apprenticed themselves to a practicing pharmacist. When Schools of Pharmacy were developed in the 1800's the apprentice would also attend classes several nights a week for "book learning". Over the centuries, pharmacists have "paid back" this apprenticeship by becoming mentors for young aspiring pharmacists seeking a professional education.

I know from my own experience as a student, the pharmacists that took the time to explain and show by example how to be a pharmacist in the real world, provided me with knowledge unattainable by books or lectures. The hands-on day to day operation of a pharmacy, either it be in the community, hospital or institutional setting, can only be experienced by performing those tasks yourself.



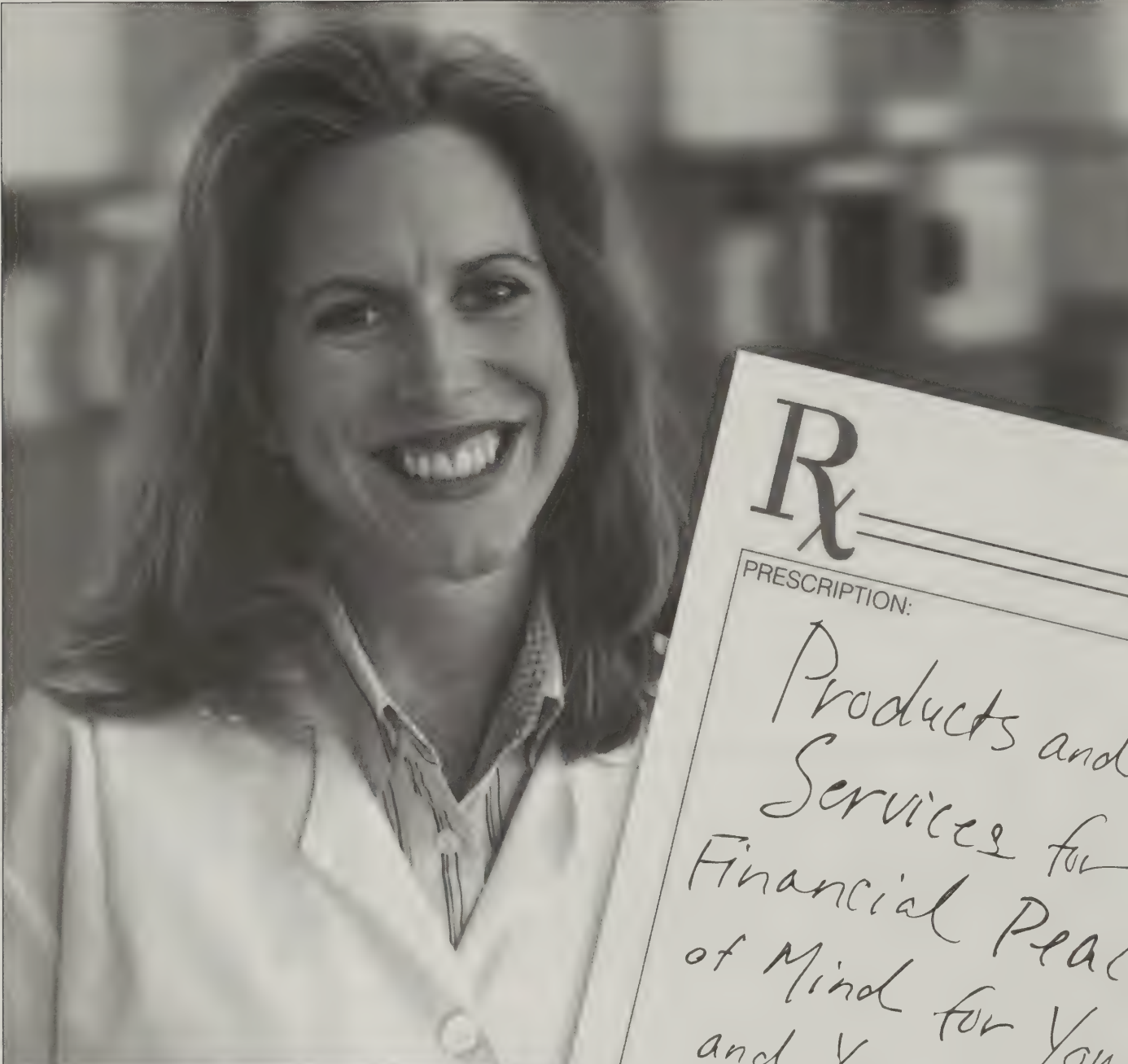
**Richard Baylis, CGP
President**

I have been a preceptor for the Experiential Learning Program (ELP) since it was started 34 years ago in 1969. Currently, I have three students assigned to me for ELP rotations. They are only three out of the sixteen assigned to me this semester by two schools of pharmacy. Two of them are from Howard University, the rest are from the University of Maryland. In addition, I mentor the Geriatric Pharmacy Resident from the Peter Lamy Center. The students inform me that some of the Phase III rotations have been postponed due to lack of preceptors. This fact was confirmed by Richard Rumrill's office although the school has repeatedly pleaded for pharmacists to act as preceptors. I am proud to be a preceptor and very proud of the students I have mentored over those years.

Our professional responsibilities are numerous, but of paramount importance are preparing those who will follow us in this profession with the experience, knowledge and ability to make us proud of them now and in the future.

I am pleading with our members and those reading this to *please sign up to be a preceptor*. It doesn't take a lot of your time and the rewards of seeing a young person succeed in our profession are great.

The University of Maryland School of Pharmacy Experiential Learning Program can be contacted one the web at www.pharmacy.umaryland.edu/elp, by e-mail elp@rx.umaryland.edu, or phone at 410-706-2432.



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Howard Schiff
Executive Director

At a recent Board of Pharmacy meeting, the new consumer member of the Board asked a question that must come to the minds of many consumers. Does the Board, or for that matter the rest of the federal pharmacy regulators, support a ban on importation because of safety concerns or to protect the economic interests of pharmacy?



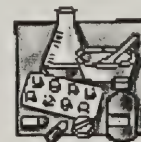
Adulteration and substitution of imported drugs have always been a problem in the United States. In 1845, upon protest to a British manufacturer regarding adulterated imported drugs, one Englishman replied that the products were "as good as the Americans would pay for." The first federal law on adulteration, the Federal Food and Drug Act, passed on June 30, 1906 and made the U.S. Pharmacopeia and National Formulary (now combined) the legally official standards. The Federal

Food, Drug and Cosmetic Act replaced the 1906 act and is the basis for the FDA. The purpose of federal legislation is to protect the public from bad, adulterated, misbranded or otherwise dangerous substances or preparations. Those of us that are old enough can remember the ban on importation of thalidomide before it was discovered that the drug caused fetal malformations. Fortunately there were relatively few cases in this country.

The Internet, advertisements in newspapers and magazines, and storefronts all proclaim to sell prescription drugs from Canada. If they're so good, why do we have an FDA? We could do away with a whole government bureaucracy. For that matter, why restrict them to prescription only? They could be sold in open air markets. Of course, I'm being facetious. This country has allowed the creation of the greatest drug delivery system in the history of the world.

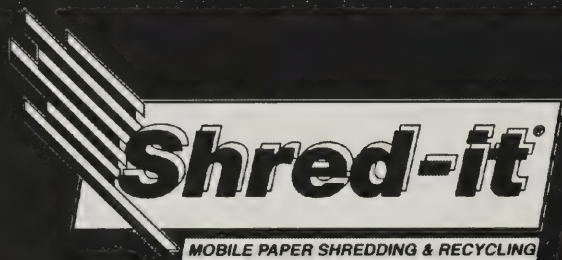


It's true that prescription drug prices are too high and the specter of our elderly choosing between medications and food is ugly. The public demands something must be done. However, the first obligation of a pharmacist is to ensure the medication the public receives is not degraded, misbranded, adulterated or otherwise dangerous.



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New Guidelines Urge more Aggressive Goals in Controlling and Treating Blood Pressure

by Nayab Hussain, Pharm.D. Candidate

A patient walks into his local pharmacy with blood pressure readings from his past doctor visits. He says to the pharmacist, "My blood pressure readings have been 124/82, 118/86, and 126/84. My doctor told me that according to some new guidelines, my blood pressure readings are above normal. How can this be because I thought "normal" readings were 120/80 and I have never had a problem with blood pressure in my life!" "Well", says the pharmacist "your doctor is correct in telling you that your readings are above normal. New guidelines have been published that would categorize your blood pressure readings as prehypertensive." "Prehypertensive?", asks the patient "what's that mean? Do I have high blood pressure now" "No, no", assures the pharmacist "but you will be at risk for developing high blood pressure in the future if you don't start taking better control of your blood pressure now."

This type of scenario is becoming very common in healthcare facilities all over the world due to new guidelines urging more aggressive goals in controlling and treating blood pressure.

In May 2003, the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure released its 7th report (JNC-VII) regarding blood pressure control. According to JNC-VII, clinicians are now to take a more aggressive approach in treating their patients with hypertension. Hypertension affects about 50 million Americans and 1 billion people worldwide and is one of the major risk factors in developing cardiovascular disease. The higher the blood pressure, the greater the chance there is of developing myocardial infarction, heart failure, stroke and kidney disease.¹ It is then very important for clinicians to properly classify patients and provide appropriate treatment as soon as possible.

Classification of blood pressure is based on 2 or more properly measured seated blood pressure readings on each of 2 or more office visits.¹ JNC-VII introduces a new category called prehypertension. For many years, blood pressure goal has been 120 mmHg systolic and 80 mmHg diastolic or lower. According to the new category, blood pressure goal should be less than 120/80. Patients with systolic blood pressures of 120-139 mmHg or diastolic pressure of 80-89 mmHg are classified as prehypertensive. These patients are now considered to be at a higher risk in developing hypertension and cardiovascular disease. Patients whose systolic blood pressure is 140-159 mmHg or diastolic blood pressure is 90-99 mmHg are classified as Stage 1 hypertension, and those with systolic blood pressure greater than or equal to 160 mmHg or diastolic blood pressure greater than or equal to 100 mmHg are classified as Stage 2 hypertension.

According to JNC-VII, the best strategy in preventing progression of blood pressure in prehypertensive patients is health-promoting lifestyle modifications. This includes weight reduction, dietary sodium reduction, aerobic physical activity and moderate consumption of alcohol. By initiating lifestyle modifications early, it will decrease blood pressure and risk of cardiovascular disease development. Patients in stage 1 and 2 will require drug therapy as primary treatment. Without any compelling indications, initial drug choice for most patients is thiazide-type diuretics. Physicians may also consider placing patients on ACE inhibitors, ARB's, β -blockers, calcium channel blockers, or combination therapy. Most stage 2 patients will require a 2-drug combination to start off with which usually consists of a thiazide-type diuretic along with ACE inhibitors, ARB's, β -blockers, or calcium channel blocker.

Compelling Indications for Individual Drug Classes

<u>Compelling indications</u>	<u>Initial Therapy Options</u>
-Heart Failure	THIAZ, BB, ACEI, ARB, ALDO ANT
-Post myocardial infarction	BB, ACEI, ALDO ANT
-High CVD risk	THIAZ, BB, ACEI, CCB
-Diabetes	THIAZ, BB, ACEI, ARB, CCB
-Chronic kidney disease	ACEI, ARB
-Recurrent stroke prevention	THIAZ, ACEI

Key: THIAZ= thiazide diuretic, ACEI= angiotensin converting enzyme inhibitor, ARB = angiotensin receptor blocker, BB= beta blocker, CCB= calcium channel blocker, ALDO ANT= aldosterone antagonist

Adherence to regimen is very important in controlling hypertension. Both the patient and clinician should agree on attainable blood pressure goals. A patient-centered strategy is the best way to achieve proper blood pressure control. Self-monitoring and education should be stressed to the patient, since the most common form of non-adherence to therapy is patient misunderstanding of the disease and treatment. Hypertension is a disease, which, unlike other diseases, is asymptomatic. This can also lead to non-adherence due to denial of illness because of lack of symptoms. Pharmacists are the most accessible health professional and because of this, many patients look to them for advice. Through proper monitoring and education, pharmacists can help patients control their high blood pressure reducing their risk of developing complications related to hypertension.

1. Bakris, GL, Black HR, Chobanian AV, et al. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure (JNC-VII report). *JAMA* 2003; 289(19): 2560-2572

2. US Department of Health and Human Services, National Heart, Lung, and Blood Institute. Reference Card from The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure (JNC-VII report). Available at <http://www.nhlbi.nih.gov/guidelines/hypertension/index.htm>. Accessed on August 26th, 2003

The Benefits of Membership

Representation—

Pharmacy and Healthcare Issues on both a regulatory and legislative level. The unique position of MPhA enables the Association to more effectively assert the position of its members than do national or specialty associations.

The MPhA's Executive Director attends the monthly meetings of the Board of Pharmacy, and participates on behalf of MPhA on various committees consisting of pharmacists and other health care professionals.

Regulations which affect pharmacists are influenced through the actions of MPhA and its Legislative Committee.

A toll-free hotline—

Members can call 800-833-7587 for answers to practice-related questions. Due to the very nature of a professional association, the resources available to MPhA are greater than those available to individual practitioners. If we cannot answer the question or concern based on MPhA's resources, the MPhA staff will try to find the information needed by the member.

Services and Programs—

Other services and programs are available as membership benefits. MPhA members are eligible for *discounted registration fees* for Association meetings and programs.

Specialized Education and Training—

To prepare for pharmacy's future MPhA offers the most recent continuing education programs.

The Mid-Year Meeting will be held Feb. 1, 2004 at a venue in central Maryland, and the Annual Convention is June 12-15, 2004 in Ocean City, Maryland. Convention attendees have plenty of time to relax and enjoy, and can earn approximately 20 continuing education credits toward their licensure renewal requirement.

Our business meetings are scheduled to give everyone a chance to participate in the Association's policy decisions.



Publications—

The "Maryland Pharmacist" journal and the "MPhA Pharmacy News" newsletter is published quarterly and monthly, respectively. In the recent past, these publications have dealt with issues which include collaborative practice, medication errors, confidentiality laws, pharmacists' workloads, the shortage of pharmacists, and the HIPAA regulations. There is a CE in each edition of the journal.

Networking—

Different locations and different practice settings, hands-on and through other State Pharmacy Associations—members have the unique opportunity to meet and develop professional relationships with practitioners in all types of health care settings. By planning and acting together, pharmacists can use a combination of knowledge and experience to benefit not only the profession, but also patients.

Pharmacy Laws and Regulations—

A copyrighted publication of the Pharmacy laws and regulations governing the practice of pharmacy in Maryland—which is updated annually—is available to members at a discounted price.

The revised lawbook contains the pharmacy laws to ensure compliance, provide information pertaining to prescribers as they impact on dispensing by pharmacists, on laws related to confidentiality of medical records, and on insurance as it effects pharmacy.

The lawbook also contains a commentary that is provided in layman's language explaining Title 12, and other statutes and regulations. It is also used as a teaching tool at the University of Maryland, School of Pharmacy for the students in the Pharm.D. program.

All parts of the revisions passed during the end of the previous year's legislative session will be included in the current edition.



Discounts and Benefits—

The Maryland Pharmacists Association has contracted with many corporations to offer member only discounts and benefits to assist you with your professional, business, and personal expenses. They include:

A Coldwell Banker Real Estate Program—

A Nest Egg Strategy—a real estate commission savings plan that can return thousands of dollars to you when you buy and sell properties in Maryland and in many other parts of the United States.

MPhA has negotiated an agreement that provides exclusive “member only” access to Coldwell Banker for substantial savings on real estate commissions. Now members can save 12% on real estate commissions on all types of properties—home, rental properties, stores, vacation property, etc. You even save thousands when you purchase property. To activate this program, call Coldwell Banker at 800-833-7356 and give this code: MPhA.



Alamo Rent-A-Car—

This program offers up to a 10% off rental as well as a 25% upgrade on your rental car needs. Contact Alamo at 800-354-2322 whenever you're planning a trip. Be sure to ask for rate code BY and use MPhA I.D. # 387298.

PEAC —Pharmacists' Education and Assistance Committee formerly Pharmacists Rehab Committee—for private, confidential referrals, call 410-706-7513 or 410-727-0746.

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Pharmacists Mutual Announces Discount for Association Members—

Algona, Iowa...Pharmacists Mutual Insurance Company announces a new discount available to association members. Members are now eligible for a premium discount on a Lincoln Benefit Life Company long-term care policy. Pharmacists Mutual Insurance Company has arranged for this discount through its subsidiary, Pharmacists National Insurance Corporation. The discount is 15% for applicants 40-64 years of age and 10% for ages 65-84. For more information about this valuable member benefit program please call Pharmacists Mutual at 800-247-5930, ext. 706 or visit their website: www.phmic.com (this is not a claims reporting site). Currently licensed in 35 states, Pharmacists Mutual has been providing exceptional products and professional service to the pharmacy profession since 1909.

Want to Place an Ad?—

Have something to sell, rent, or trade? Need a pharmacist? Looking for a new position? MPhA members can place a classified ad in the *Maryland Pharmacist* and reach more than 1,000 pharmacists for free. All ad copy is subject to approval and space availability. Reservations are due the first of the month preceding issue month. To place an ad, send your typewritten copy to MPhA, 650 W. Lombard Street, Baltimore, MD 21201-1572, fax to 410-727-2253, or e-mail mpha@starpower.net.

If you have any questions about these member benefits please feel free to call the MPhA office at 410-727-0746 or e-mail us at mpha@starpower.net.

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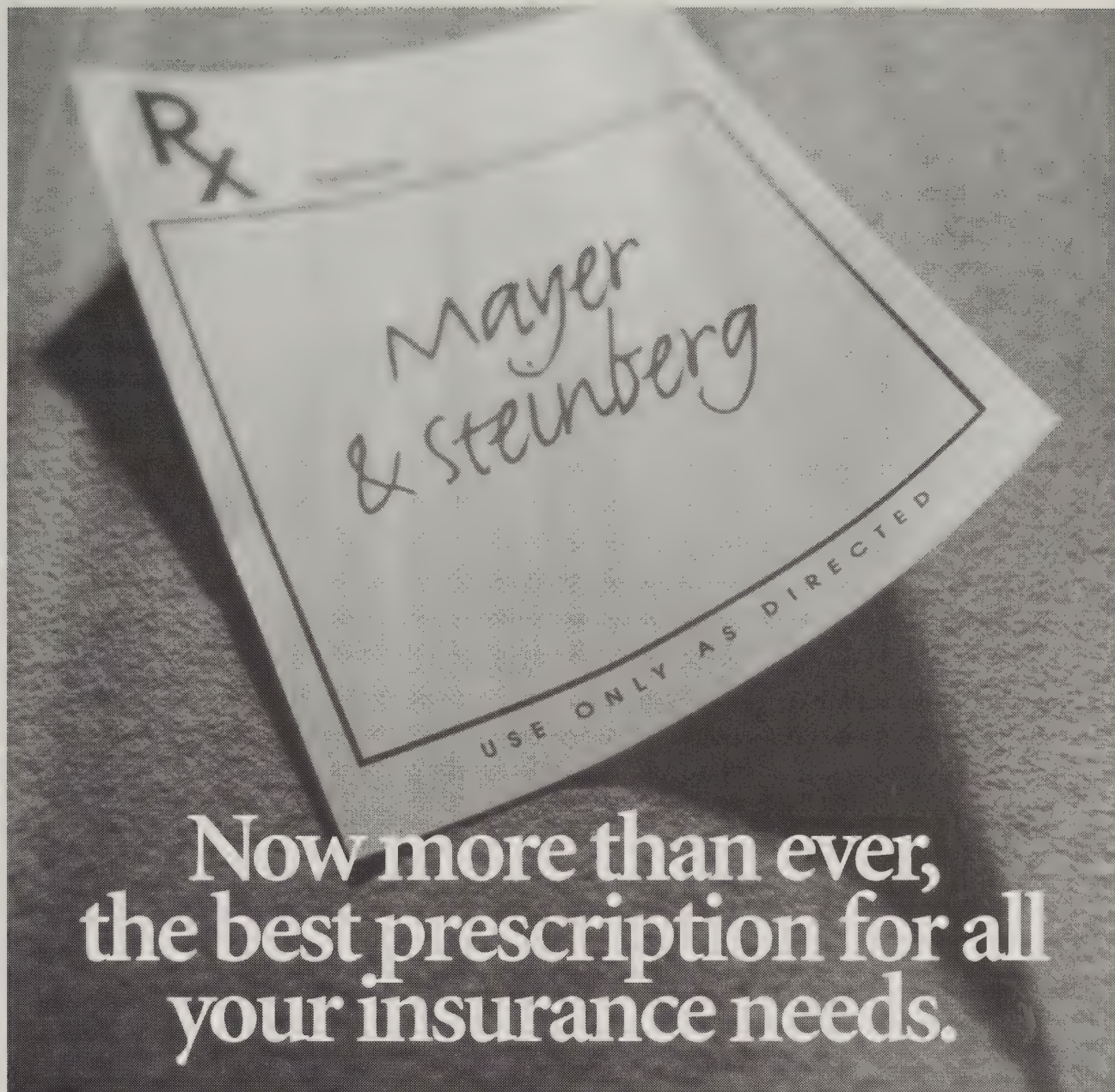
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Important Tax Information

Dues for MPhA are not deductible as charitable contributions for Federal Tax purposes. However, they may be deductible as ordinary and necessary business or miscellaneous expenses. Because of tax law changes affecting association membership dues deductibility, you may not deduct any portion of your dues which goes towards lobbying local, state, or national government agencies. MPhA has determined that the deductibility of your MPhA dues is limited to no more than 85% of your total dues.

NOTE: If you are interested in serving on one of the following: Convention, Legislative, Nominating, Resolutions, Member Services or Building Committee; or the Employee Pharmacist Task Force, please contact the MPhA office at 410-727-0746 or mpha@starpower.net. Any member in good standing may serve. Thank you.



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Prilosec OTC

For the millions of Americans suffering from occasional heartburn, there is an increasingly wide selection of medications available without a prescription at the local drug store. While these medications are effective for occasional or even frequent heartburn, they are only intended to treat symptoms for a limited time period. In fact, these medications should not be taken more often or for longer than indicated unless directed by a doctor because that could be a sign of a more serious condition, such as acid reflux disease.

Since pharmacists are on the front-line, answering consumers' questions and offering advice, consumer education about the numerous OTC choices for treating heartburn is important, especially with Prilosec OTC hitting pharmacy shelves, September 15.

Consumers need to understand Prilosec OTC is a different type of medicine from antacids and other acid reducers. It works differently and does not provide immediate relief (1-4 days for full effect) and unlike antacids and other acid reducers, OTC Prilosec should be used only for one 14-day treatment cycle every four months. If symptoms continue or return after 14 days, it is important to see a doctor, who can help choose the most appropriate treatment.

"Patients should know that chronic use of over-the-counter medications could be a sign that they have a more serious health problem," says Dr. Dr. Lucinda Harris, assistant professor of clinical medicine at The Weill Medical College of Cornell University. "If patients don't find heartburn relief after taking an over-the-counter medication for two weeks, they should see a doctor for a proper diagnosis. Their doctor can best help them evaluate treatment options – both prescription and over-the-counter."

Acid reflux disease is a complex condition with many degrees of severity, ranging from symptoms only to erosive esophagitis, which occurs when acid reflux damages the lining of the esophagus. Complications associated with acid reflux disease can include:

- Esophageal stricture – a narrowing or closing of the esophagus. It is usually accompanied by pain and difficulty swallowing and can cause food to get trapped in part of the esophagus. A severe stricture may need surgery.

- Barrett's Esophagus – a serious complication that can, in rare cases, lead to cancer. The lining of the lower esophagus changes to resemble the lining of the intestine or stomach as the body tries to protect itself from further injury due to stomach acid. However, when this happens, there is an increased risk of developing a type of esophageal cancer called adenocarcinoma of the esophagus.

Dietary and Lifestyle Tips To Share With Consumers

The following are general measures the consumer can take to reduce heartburn and reflux:

- Elevate the head of the bed six to eight inches
- Lose excess body weight
- Stop smoking
- Avoid large portions at meals. Instead, eat smaller, more frequent meals
- Avoid:
 - Chocolate
 - Coffee, tea and alcohol
 - Fried and fatty foods
 - Mint products (i.e., peppermint, spearmint)
 - Carbonated beverages, and citrus fruits or juices (orange juice)
 - Tomato sauce, ketchup, mustard and vinegar

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Over-the-Counter Drugs To Be Covered by Health Care Flexible Spending Accounts

IR-2003-108 Sept. 3, 2003

WASHINGTON — Today, the Treasury Department and the IRS announced over-the-counter drugs can be paid for with pre-tax dollars through health care flexible spending accounts. Treasury and IRS issued guidance clarifying that reimbursements for nonprescription drugs by an employer health plan are excluded from income. Thus, reimbursements by health flexible spending arrangements (FSAs) and other employer health plans for the cost of over-the-counter drugs available without prescription are not subject to tax if properly substantiated by the employee.

"Flexible Spending Accounts are an important tool in helping people meet their health care costs," stated Treasury Secretary John Snow. "Since many prescription drugs have moved to the over-the-counter market, this action today makes paying for them a little bit easier to swallow."

"Flexible Spending Accounts were established under the tax code to provide incentives for better health care," said IRS Commissioner Mark W. Everson. "This action is a sensible expansion and simplification of the program consistent with existing law."

Drugs are increasingly becoming available over-the-counter without prescription. Many health plans no longer cover the cost of these drugs as over-the-counter. While an over-the-counter drug is less expensive than the prescription drug, the cost to many consumers increases because the price paid by the consumer for the over-the-counter drug is greater than the co-payment by the consumer when the drug was covered by insurance. This is especially an issue for individuals who remedy chronic health problems by regularly taking an over-the-counter medicine.

Revenue Ruling 2003-102 explains that the statutory exclusion for reimbursements of employee health expenses is broader than the itemized deduction for medical expenses (which does not apply to nonprescription drugs). Thus, the guidance clarifies that employer reimbursements of employee health expenses that are nonprescription drugs, including reimbursements through health FSAs and Health Reimbursement Arrangements (HRAs), are excluded from income like other employer reimbursements of employee health expenses. This will result in savings to consumers with access to employer plans who may purchase nonprescription drugs.

However, for purposes of the itemized medical expenses deduction, the cost of such over-the-counter drugs continues to be non-deductible. In addition, the cost of dietary supplements that are merely beneficial to the employee's health are not excluded from income.

Rev. Rul. 2003-102 will be published in Internal Revenue Bulletin 2003-38, dated Sept. 22, 2003. It is available on the IRS Web site at www.irs.gov.

#

Continuing Education for Pharmacists

Volume XX, No. 12

Patient Counseling: Alzheimer's Disease: Part 1: The Disease

Thomas A. Gossel, R.Ph., Ph.D.
Professor Emeritus
Ohio Northern University
Ada, Ohio

and

J. Richard Wuest, R.Ph.,
Pharm.D.
Professor Emeritus
University of Cincinnati
Cincinnati, Ohio

Goal. The goal of this lesson is to discuss important concepts of Alzheimer's disease.

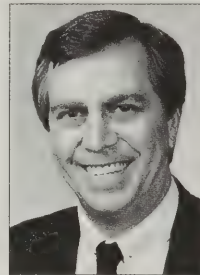
Objectives. At the conclusion of the lesson, successful participants should be able to:

1. recognize symptoms of Alzheimer's disease;
2. select from a list the risk factors of the disease;
3. exhibit knowledge of pathophysiology and prognosis of Alzheimer's disease; and
4. demonstrate an understanding of how to counsel patients and/or their caregivers on Alzheimer's disease.

Four million persons in the U.S. are reportedly affected with Alzheimer's



Gossel



Wuest

disease. This number may not appear to constitute a significant health problem. For example, compared to hypertension with more than 50 million sufferers in the U.S., Alzheimer's disease can easily get lost in the shuffle. It ranks twelfth as a cause of death in the U.S. The cost of caring for persons with Alzheimer's disease is estimated to exceed \$100 billion annually, and is expected to increase severalfold in the coming decades.

Part 1 of this two-part lesson series describes key features of the etiology and pathogenesis, symptoms, risk factors, and prognosis of Alzheimer's disease. Part 2 will include pharmacologic and non-pharmacologic approaches to management of Alzheimer's disease, as well as patient/caregiver advice.

Dementia

The fourth edition of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-IV) describes dementia as the development of multiple cognitive deficits severe enough to impair occupational or social functioning. The deficits must embody a noted decrease from previously higher levels of functioning. Cognitive deficits of dementia always include memory loss, along with at least one of the following: (a) failure to recognize familiar objects,

(b) impairment of motor activities, (c) retrogression of language skills, and (d) generalized inability to function normally.

Dementia is an expected outcome of a large variety of pathologies, only one of which is Alzheimer's disease. Still, Alzheimer's is the most common cause of dementia in western countries. Others include cerebrovascular deficiency disease, traumatic brain injury or brain tumor, Huntington's disease, Parkinson's disease, and vitamin B₁₂ deficiency.

Mild dementia is commonly and erroneously confused with memory impairment that may accompany aging, although differentiating between symptoms associated with the normal aging brain and dementia of Alzheimer's disease is straightforward. With normal aging, deficits in memory can usually be compensated for by using memory-enhancement aids such as written lists. This type of memory loss is not as disabling as that associated with dementia of the Alzheimer's type.

Iatrogenic Causes. Certain medications can affect cognition. This is especially true for older persons taking multiple drugs. Identifying dementia that is drug-related (i.e., iatrogenic) can help rule out an erroneous diagnosis of Alzheimer's disease. Table 1 lists representative classes of medications that can cause cognitive impairment. This list was compiled by a consensus panel of the U.S. Department of Health and Human Services.

Alzheimer's Disease

The disorder that today is known as Alzheimer's disease was first de-

This lesson is provided by an
educational grant from

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Table 1
Examples of Medications that May Cause Cognitive Impairment

Antiarrhythmic agents
Antibiotics
Anticholinergic agents
Antidepressants
Anticonvulsants
Antiemetics
Antihypertensive agents
Antineoplastic agents
Antimanic agents
Anti-Parkinsonian agents
Antihistamines/decongestants
Cardiotonic agents
Corticosteroids
H₂ receptor antagonists
Immunosuppressive agents
Narcotic analgesics
Muscle relaxants
Nonsteroidal anti-inflammatory agents
Radiocontrast agents
Sedatives

From: U.S. Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research. Nov. 1996.

scribed by Dr. Alois Alzheimer in 1906. In 1901, a 51-year-old woman in a Frankfurt (Germany) hospital for the mentally ill was attended by Dr. Alzheimer. Over the ensuing years, she displayed progressive cognitive disability. Following her death in 1906, autopsy revealed severe atrophy of neuronal tissue in the brain. Dr. Alzheimer reported the presence of numerous abnormal clumps (now called amyloid plaques) and tangled bundles of fibers (now called neurofibrillary tangles), that are today identified as histopathological hallmarks of the disease. A textbook of psychiatry, authored by his colleague and published in 1907, first named the newly described clinical syndrome *Alzheimer's disease* in reference to Dr. Alzheimer's classic observation. Today, Alzheimer's disease is recognized as a progressive degenerative condition of the brain that can impact patients for the rest of their life.

The age-specific rates of incidence of clinically diagnosed

Alzheimer's disease are summarized in Table 2. These data were obtained by evaluating individuals aged 65 and older who lived in the Boston area. Initially free of symptoms, "probable" Alzheimer's disease developed in 95 of 642 subjects who were followed over a period of 4.3 years. From this observation, the annual incidence rate of clinically diagnosed Alzheimer's disease for each age group was estimated. Other studies have subsequently reported similar age-related increases in incidence although lower rates in persons over 85 years have also been reported. If the incidence rates in the Boston study are applicable to the general population, 6 percent of men and 16 percent of women who live to an average life expectancy will develop Alzheimer's disease.

In Dr. Alzheimer's day, approximately 4 percent of the U.S. population was over age 65. Today, the over-65 group is estimated to include approximately 12 percent of the population. This number is projected to increase to 20 percent of the population by 2025. Because persons over age 80 are most likely to be affected with Alzheimer's disease, the social and economic implications to patients' families and the country at large are massive.

While Alzheimer's disease may be diagnosed as early as the fourth decade of life, it is rare for these younger people to exhibit sufficient symptomatology to be officially diagnosed with the disorder. The disease course may persist for up to 25 years after onset, depending on the patient's age and general health, but the average duration is eight to 10 years. This timing will likely increase as health care continues to improve in the future.

Symptoms. Symptoms (Table 3) appear so gradually that the disease is usually not detected until many years after onset. Oftentimes a decade or longer passes before behavior peculiarities and decreasing intellect are finally recognized.

Early in the disease, mental impairment may be the only identifi-

Table 2
Estimated Rate of Occurrence of Alzheimer's Disease by Age

Age (years)	Occurrence (%)
65-69	0.6
70-74	1.0
75-79	2.0
80-84	3.3
85 & older	8.4

See text for discussion of the source of these figures.

able symptom, but its severity increases over time. Recent memory, the first cognitive process to decline, may be initially ascribed to benign forgetfulness. Long-term memory is retained the longest. Early on patients show confusion in identifying spouse and family, but eventually fail to recognize them at all. They become completely disoriented as to time and place. Their speech and ability to understand become impaired. It becomes difficult for them to perform simple chores. Decisions and ability to plan become extremely difficult. While some victims become exceedingly restless, others become almost listless.

Activities that were formerly enjoyable are no longer pursued. Personality changes are prominent. The patient may be depressed or delusional. Other times he or she will be delirious, paranoid, fearful, and even violent. Delusions and assaultiveness are especially common at night. Eventually the patient may become mute, rigid, incontinent, bedridden, and incapable of self-care. Patients may develop hyperactive tendon reflexes along with primitive sucking and snouting reflexes. Myoclonic jerks (sudden muscle contractions) may appear spontaneously or in response to auditory or physical stimuli.

When the onset of disease occurs at an older age, the average time from appearance of symptoms to death is about five years, but may be shorter than one year. Duration is longer (as stated earlier, average eight to 10 years) when symptoms appear earlier in life.

Table 3
Symptoms of Alzheimer's Disease

Mild symptoms

- Confusion and memory loss
- Being disoriented or getting lost in familiar surroundings
- Changes in personality and judgment

Moderate symptoms

- Difficulty with the activities of daily living such as bathing or feeding
- Anxiety, suspiciousness, agitation, or depression
- Problems with sleeping
- Wandering or pacing
- Difficulty recognizing family and friends

Severe symptoms

- Loss of speech
- Loss of appetite and weight loss
- Loss of bladder and bowel control
- Total dependence on others for daily living

Source: www.ama-assn.org/public/journals/patient/archive/pat1107.htm

The actual cause of death is often an opportunistic infection such as pneumonia. Patients ultimately become so debilitated by their disease that their immune system deteriorates to the extent that they are unable to combat common infections. Malnutrition and heart disease are other causes. Or, patients may die from traumatic injury after falling or another accident. Even if the individual has no other serious illness or accidents, the loss of brain function itself can cause death.

Risk Factors. Numerous risk factors that increase the chance for developing Alzheimer's disease have been identified. Major inciters include advancing age and a family history of the disease. Collectively, these account for approximately one-half the attributable risk.

The site of residence before age 18 and the number of siblings have been correlated with eventual development of Alzheimer's disease. In a study of individuals living in the Seattle area, the researchers

reported that growing up in a family along with five or more siblings increased the risk of Alzheimer's disease development by 39 percent. The lowest risk was shown for persons who grew up in the suburbs or rural areas contrasted to urban settings. Better health care and more favorable economic considerations outside some urban centers have been implicated as being partly responsible for the reduced incidence of Alzheimer's disease.

Additional risk factors include female gender, head injury and type 2 diabetes mellitus. A prospective study of elderly subjects revealed that the presence of type 2 diabetes mellitus almost doubled the risk of Alzheimer's disease. Studies have suggested that estrogen use during the postmenopausal years is associated with decreased frequency of Alzheimer's disease, although this association remains somewhat controversial.

Negative Risk Factor. Investigations have suggested that there might be truth to the "use-it-or-lose-it" hypothesis. It has been shown that persons who participate frequently in cognitively-stimulating activities seem to have a decreased risk of Alzheimer's disease. The research has focused on everyday activities including reading books, newspapers or magazines; working crossword and other puzzles or playing cards; and visiting art galleries and museums. When cognitive activity is stimulated, these individuals have a lowered risk of Alzheimer's disease. A similar negative correlation has been reported for persons who were able to express complex written language in early adulthood.

Pathophysiology. Knowledge of the risk factors for Alzheimer's disease has aided in identification of some of its possible causes. Much remains unknown, however. The most prevalent theories that attempt to define the cause(s) include an involvement of the neuritic (senile) plaques and neurofibrillary tangles that Dr. Alzheimer described. Detected in the brains of Alzheimer's

patients at autopsy, their presence offers testimony that strongly suggests their underlying cause(s) may be the actual etiologic trigger for the disease. In reality, there is probably no single cause, but several factors that affect each person differently. The vast preponderance of histologic changes to the brain's tissues are quantitative, rather than qualitative.

Genetics. The role of genetics in the pathogenesis of Alzheimer's disease is an active focus of research, although in about 90 percent of cases, there is no clear genetic link. Nevertheless, a family history of Alzheimer's disease is a major risk factor for developing the disease.

In family members who develop the malady before age 60, a mutation in the amyloid precursor protein gene (beta-APP) has been identified. The action of this gene is not known completely. It may function to stimulate cell proliferation and adhesion. It may also support the nerve growth factor. In addition, investigators have long known that patients with trisomy 21 (Down's syndrome) consistently develop the classic neuropathologic hallmarks of Alzheimer's disease if they survive beyond age 40. These patients possess an extra chromosome 21. The gene that encodes the beta-APP protein is located on chromosome 21. There may also be other genetic links between these two brain disorders. Moreover, there have also been suggestions linking various other chromosomal abnormalities to Alzheimer's disease.

Neuritic Plaques. The plasma protein apolipoprotein E has been shown to be present in neuritic plaques in brains of Alzheimer's patients. Apolipoprotein E is normally involved in transport of cholesterol. The result of investigation has reported that 34 to 65 percent of Alzheimer's patients have the ApoE allele, contrasted to 24 to 31 percent of the unaffected population. The ApoE allele may be involved in formation of beta-amyloid, a protein containing 39 to 42 amino

acids found in the plaques of brains of patients with Alzheimer's disease. Normally soluble, beta-amyloid protein is secreted by brain cells and cleared from the site. In Alzheimer's disease, however, it is believed to become insoluble and thus collect within intracellular spaces to form the neuritic plaques. These plaques damage brain cells and attract reactive cells that incite further damage. This theory does not describe the etiology of Alzheimer's disease in detail because the brains of many asymptomatic persons will show significant amyloid-containing plaques upon postmortem examination.

There is considerable thought given to whether beta-amyloid can evoke brain cell membranes to leak choline. It is held that choline aids in storage and retrieval of memory. The decline in cognitive function associated with Alzheimer's disease relates to reduction in transmission by cholinergic pathways in the basal forebrain. A primary goal of therapy with contemporary drugs, and one that shows positive improvement in treatment of Alzheimer's disease, is to improve cholinergic function.

Neurofibrillary Tangles.

Tau is a protein that is normally present to stabilize microtubules in brain cells that are associated with the cells' protein-transport system. It is theorized that cell injury and death occur from tangles in neuronal cytoplasm as tau protein is abnormally phosphorylated and forms twisted neurofilaments. These, in turn, form the neurofibrillary tangles that disrupt cell functions, leading to cell death. Tau formation correlates positively to disease severity. The presence of neurofibrillary tangles alone does not determine the presence of Alzheimer's disease since they may also be found in the normal aging brain. At the same time, a history of classical symptoms of dementia along with the presence of both neuritic plaques and excessive neurofibrillary tangles on postmortem examination are strongly indicative of classic Alzheimer's

disease.

Free Radicals. There is one other theory on the genesis of Alzheimer's disease that is currently receiving much attention. It associates excessive free radicals with resultant damage from oxidation of nerve cells. Free radicals are highly reactive substances. They are believed to play a key role in a number of diseases including heart disease and cancer, as well as Alzheimer's disease. While free radicals are required to maintain normal functions such as combating infection, excessive quantities can lead to release of cytotoxic chemicals.

Free radicals attach to protein, fat or DNA, and upset the normal functioning of cell membranes which in turn ultimately causes cell death. This has led to increased interest in the use of vitamins C and E, trace elements such as selenium, and other less familiar antioxidants in the prevention and treatment of Alzheimer's disease.

Public Health Impact

Management of Alzheimer's disease will become increasingly challenging to the nation's health care planners, providers, and payers. This is particularly true since the increasing 80-year-old-plus population is affected by Alzheimer's disease in greatest numbers. At present, the average lifetime cost of care for a patient with Alzheimer's disease is approximately \$174,000.

The costs to the nation's health care system would be decreased dramatically if symptom onset could be delayed. Since the prevalence of Alzheimer's disease approximately doubles with each five years of advancing age, postponing onset for this period of time would reduce the prevalence by one-half. Research efforts directed toward prevention or delay of symptom onset are ongoing and encouraged.

Drugs approved for use in Alzheimer's disease result in significant cost savings over time. This savings is due primarily to their

effectiveness in prolonging the patient's time in the home before needing skilled nursing care. Moreover, the drugs increase patient quality of life which in turn reflects upon enhanced quality of life for their families and/or caregivers.

Counseling Caregivers

At present, seven out of 10 patients are attended to at home. It is estimated that for every one patient with Alzheimer's disease, three other family members are directly affected emotionally, socially, perhaps physically, and certainly, financially. Alzheimer's disease is the major cause for placement of persons in nursing facilities.

Pharmacists' advice is oftentimes conveyed to caregivers, rather than directly to Alzheimer's disease sufferers. Caregivers should be advised to assure that the patient complies as closely as possible with the prescribed therapeutic regimen. The caregiver should be advised to contact the patient's physician as soon as any change is noted in the patient's mental or physical condition. More on patient and caregiver counseling will be presented in Part 2 of this lesson series.

Conclusion

In the concluding lesson, treatment with cholinergic inhibitor drugs will be emphasized, and specific information for patients and their caregivers will also be presented.

Continuing Education Quiz

This month's questions are taken from the article on "Patient Counseling: Alzheimer's Disease: Part 1: The Disease." Circle your answers to the following questions and mail the entire page to Maryland Pharmacist CE, 650 W. Lombard Street, Baltimore, MD 21201-1572. There is no charge for this quiz for MPhA members (non-members \$ 10.00). The completed quiz for this issue must be received by 12/15/05. A continuing education certificate for one and one-half contact hours (0.15 CEUs) will be mailed to you within six to eight weeks. Please type or print clearly. ACPE# 129-144-02-012-H01.

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1. In addition to Alzheimer's disease, another cause of dementia is a deficiency of:

- a. vitamin A.
- b. vitamin B₁₂.
- c. vitamin C.
- d. vitamin D.

2. Dementia that is caused by drugs is referred to as:

- a. nosocomial.
- b. idiopathic.
- c. neurotoxic.
- d. iatrogenic.

3. All of the following are examples of drugs that may cause cognitive impairment EXCEPT:

- a. antidepressants.
- b. antimanic agents.
- c. cholinesterase inhibitors.
- d. corticosteroids.

4. In Alzheimer's disease, the first cognitive process to decline is:

- a. recent memory.
- b. long-term memory.

5. The delusions and assaultiveness exhibited by some patients with Alzheimer's disease are especially common:

- a. in the morning.
- b. around noon.
- c. mid-afternoon.
- d. at night.

6. The actual cause of death in patients with Alzheimer's disease is often an opportunistic infection such as:

- a. encephalitis.
- b. cystitis.
- c. pneumonia.
- d. herpes.

7. Which of the following diseases has been revealed to almost double the risk of developing Alzheimer's disease?

- a. Diabetes mellitus
- b. Multiple sclerosis
- c. Osteoporosis
- d. Shingles

8. Persons with which of the following disorders consistently develop the classic neuropathologic hallmarks of Alzheimer's disease?

- a. Graves' disease
- b. Down's syndrome
- c. Raynaud's disease
- d. Hashimoto's syndrome

9. Which of the following proteins is found in the plaques of brains of Alzheimer's patients?

- a. Acetylcholine
- b. Beta-amyloid
- c. Gamma aminobenzoate
- d. Delta-tocopherol

10. The decline in cognitive function associated with Alzheimer's disease relates to reduction in transmission by:

- a. alpha-adrenergic pathways.
- b. beta-adrenergic pathways.
- c. cholinergic pathways.
- d. dopaminergic pathways.

CORRECTION: The correct ACPE number for Patient Counseling: Management of Sore Throat which appeared in the Jan./Feb./Mar. 2002 issue of the Maryland Pharmacist is 129-144-01-011-H01.



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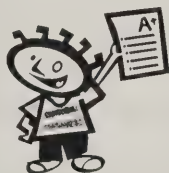


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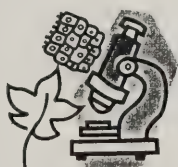
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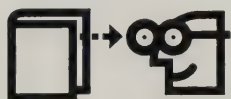
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Pharmacist Licensure Examination

For the results of the Pharmacist Licensure examination visit the Maryland Board of Pharmacy's website at: www.dhmd.state.md.us/pharmacyboard/pharmlic/0600rost.htm. The results are updated every Friday.

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